EPA Registration No. 39967-137 Vol. 7

Material to be added to an e-Jacket/Jacke

Reg. No. 716:54-6

1. ☑ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top/newest)
   - ☐ Description: (PDF page number, i.e., "before page 45")

2. ☐ Send to Data Extraction contractors this material:
   - ☐ Newly stamped accepted label
   - ☐ Notification
   - ☐ New CSF
   - ☑ Other: Amendment

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: S Grigoby

Phone: _____ Division: AI

Date: 7/15/10

Created July 21/20

TASK ASSIGNMENT FORM

Antimicrobial Division/Regulatory Management Branches I/II

A	Completed by Product Manager

PRODUCT REVIEWER: Stacey Grigsby	**RMB I I TEAM 34**
Description of Action: Amendment	**EPA File Symbol/Reg No.: 71654-6**

FQPA Action Code: 302	**Non-FQPA Action Code:** _____	**Fee for Service Action Code:** _____
Decision No. 433297	**Submission No.** 872542	**Fee for Service Fee: $** _____

	MONTH	DAY	YEAR
APPLICATION DATE	4	13	2010
EPA PIN DATE	4	16	2010
REVIEWER ASSIGNED DATE	5	3	2010
DATE DUE TO PM			2010
DATE DUE OUT OF AGENCY	7	15	2010

Type of Data:	Product Chemistry	Acute Toxicology ☐	Efficacy ☐	Environmental Fate ☐	Ecological Effects ☐	Chronic Toxicology ☐	Exposure ☐

Comments:

Amendment – Added clarifying language to pages 10 and 11

ATTACHMENTS: __X__ **LABELING** __ **CSFs** _____ **DATA** ____ **OTHER**

B	For Arctic Slope Contract Only

Contractor:	**Contract No.:**	**TOPO/Alt. TOPO:**
Draft Task: Signature _____ ____ (Est. hrs)	**Final Task: Signature** _____ _____ (Total hrs)	

C	**Reviewers Comments:**
Response Code: 1165	**Response Date:** JUL 15 2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 15 2010

Ms. Susan M. Schaner
E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
P.O. Box 80402 (E403-3224D)
Wilmington, DE 19880-0402

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: **Virkon® S**
EPA Registration Number: 71654-6
Application Date: April 13, 2010
Receipt Date: April 16, 2010

Dear Ms. Schaner:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable with conditions.

Proposed Amendment

- Label Amendment: Adding Clarifying Language

Conditions
Revise the label as follows:

1.) The organism being mitigated by this product is *Brucella abortus* , a bacteria. Revise the nomenclature for *Brucella abortus* on page 10 by deleting the phrase, "bacteria of."

2.) PRN 2005-1, Guidance for Mandatory and Advisory Labeling Statements, states that: **"Mandatory statements**, which commonly use imperative verbs such as "must" or "shall", either require action or prohibit the user from taking certain action. **Advisory statements** generally provide information, either in support of the mandatory statements or about the product in general. **To ensure that the intent of each labeling statement is clear, mandatory statements need to be clearly distinguishable from advisory statements."** Therefore, revise the "Directions for Use" on pages 10 thru 14 by deleting the terms, "recommended" and "should." Replace "should" with "*must.*"

3.) The product must support clear instructions on how to utilize this product as a fogger in hatcheries and animal housing facilities by stating the following:

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

Follow General Instructions to remove poultry and/or animals from room to be treated. Close room off, so fog is confined to room to be treated. Apply Vircon S at dilution rate of 1:200 (0.5%) at an application of 1 gallon per 430 ft^2 of floor space. Use a mechanical or plumbed in misting system designed for water-

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

based applications with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse.

Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves, and pants.

4.) Delete directions for "Air Sanitizing" and "Aerial Spraying to control airborne diseases" on pages 8 and 10 because there is no data on file to support this claim. If you would like to make this claim, you must submit efficacy data in accordance with DIS/TSS before a product may make this claim on the label.

5.) The Directions on pages 8 -13 except the "Broiler/Breeder Houses" and "Greenhouses and Horticulture" directions are incomplete because they do not indicate how to apply the use solution, the contact time, or to allow the treated surfaces to air dry or rinse with potable water. Therefore, add the following statements to each direction: *Saturate surfaces with 1% solutions of Vircon with cloth, mop, mechanical spray, or sponge for period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.*

6.) Qualify "infectious disease wards" on page 10 as being limited to animal facilities by stating "*animal* infectious disease wards."

7.) Revise the phrase, "disease organisms" on page 13 by deleting the term, "disease." The intent of this product is to mitigate microorganisms on hard nonporous surfaces not to protect or prevent animal infections. The use of the term, disease, implies that the product is protecting the animals from contracting a disease which is false and misleading.

8.) The "Storage and Disposal" statements on page 13 must be revised in compliance with the Container Rule and PR Notice 83-3 by stating the following:

Storage and Disposal
Do not contaminate food, feed, or water by storage and disposal.
Pesticide Storage: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides solutions or rinsate is a violation of Federal law. If these wastes cannot be disposed of according to use instructions on the label, contact your State Pesticides or Environment Control Agency, or the Hazardous Waste Representative at an EPA regional office for guidance.
Container Disposal: Nonrefillable container. Do not refill or reuse this container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal Repeat procedure two more times. Then, offer for recycling or reconditioning, if available. If not, dispose of container in a sanitary landfill.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

General Comments

A stamped label with conditions is enclosed for your records. Submit a copy of your final printed label before distributing or selling the product bearing the revised labeling.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacey@epa.gov . When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,

Jacqueline McFarlane
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped label

	CONCURRENCES							
SYMBOL								
SURNAME								
DATE								

Virkon® S

Disinfectant and Virucide

BROAD SPECTRUM DISINIFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] [OPT]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against
•Viruses
Including Canine Parvovirus [OPT]
•Bacteria
•Fungi

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 15 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 71654-6

ACTIVE INGREDIENTS:	
Potassium peroxymonosulfate.....	21.41%
Sodium Chloride.....	1.50%
OTHER INGREDIENTS.....	77.09%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

See Inside Booklet for Additional Precautions [OPT]
See leaflet for additional directions for use [OPT]

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

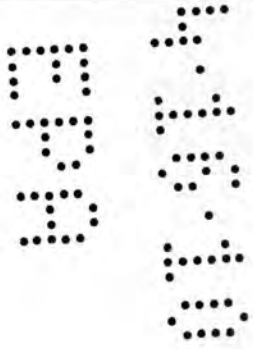
Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6 EPA Est. No. XXXXX-YY-ZZZ

<Lot or batch #>

Front Panel Continued

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice.
If on Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice.
If Swallowed:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
HOT LINE NUMBER	
For 24-hour emergency information on this product, call 1-800-441-3637 (US & Canada) or 1-302-774-1139 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	



Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1-800-441-7515
Outside the US, contact: 1-302-774-1000

US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

ANIMAL AND ZOONOTIC PATHOGENS

BACTERIA

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella enterica
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

Not approved in California for use against the following bacteria:
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycoplasma hyopneumonia
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Equine Herpes Virus (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

Not approved in California cont.

Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Hog Cholera Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagrophytes (2%)

Not approved in California for use against the following fungi:
Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

PLANT PATHOGENS
Not approved in California for use against plant pathogens:
Alternaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
Corrosive statement refers to powder only not in use-diluted solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts – *Not Approved for this use in California*), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."

Respiratory illnesses attributable to Pandemic 2009 H1N1are caused by influenza A virus. Virkon® S [OPT] [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). [OPT]

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus. [OPT]

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). [OPT]

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu). [OPT]

Kills Pandemic 2009 H1N1 influenza A virus. [OPT]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

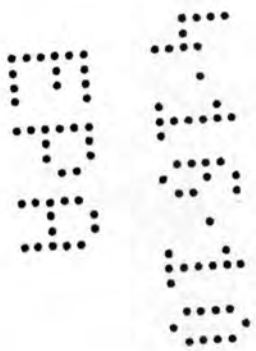
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.



Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT]

Powder

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Quart	*0.15 ounces**	*0.3 ounces*	*0.7 ounces*
1 Gallon	*0.65 ounces**	*1.3 ounces*	*2.7 ounces*
10 Gallons	*6.7 ounces**	*13.4 ounces*	*26.7 ounces*
50 Gallons	*33.4 ounces**	*66.8 ounces*	*133.5 ounces*

Measuring cup provided.

Tablet

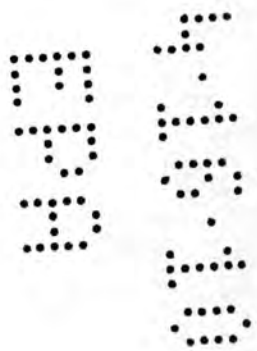
Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Pint		*1 tablet*	*2 tablets*
1 Quart	*1 tablet**	*2 tablets*	*4 tablets*
1 Gallon	*4 tablets**	*8 tablets*	*16 tablets*

Sachet

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 gallon	-	*1 Sachet*	*2 Sachets*
2 Gallons	*1 Sachet*	*2 Sachets*	*4 Sachets*

* The 0.5% solution currently is not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]



POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella enterica, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts – *Not Approved for this use in California*) Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori.

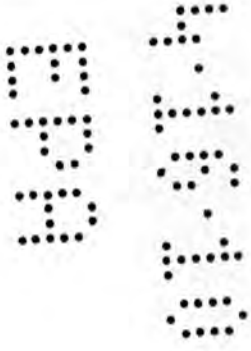
HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.



SWINE PRODUCTION

CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens; Fungi of Trichophyton mentragrophytes (2%). *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme, Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION

CONTROLS: Viruses of Equine herpes virus Type 1 and Type 3 and Equine Influenza. Bacteria of Brucella abortus, Clostridium perfringens, Dermatophilus congolenisis (at 2%), Pseudomonas aeruginosa, Salmonella typhimurium and Staphylococcus aureus. Fungi of Trichophyton mentagrophytes (at 2%). *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme,Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4; Fungi of Trichophyton mentragrophytes(2%). *Not approved in California for use against the following organisms:* Bacteria of Moraxella bovis and Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. Fungi of Trichophyton mentragrophytes(2%). *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned

with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers: *Not approved use in California:* Treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

Disease Organism	Dilution Rate	Oz./Gal.
PCV2 Virus (PMWS)	1:200	0.7

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges or other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

PESTICIDE STORAGE:

For pails, [jugs], [bottles]: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

For [sachet] [pouch] [packet] [bag]: Store in a cool dry place. Keep out of reach of children. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

[**For spray bottle with in-use solution:** Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

CONTAINER DISPOSAL: **Nonrefillable container. Do not reuse or refill this container.** [Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment.] Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DuPont Chemicals and Fluoroproducts
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemicals and Fluoroproducts

April 13, 2010

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
Jacqueline McFarlane (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: Virkon® S, EPA Registration #: 71654-6
Non-PRIA Action fast track amendment, no data

Dear Ms. McFarlane,

On behalf of E. I. du Pont de Nemours, I wish to submit a fast track amendment for the above referenced product for the purpose of clarification language.

On pages 10 and 11 of the label we have highlighted language that differ from the last accepted label.

Enclosed in support of this amendment are the following:

- Completed application for Pesticide Registration (EPA form 8570-1) – dated April 12, 2010
- Four copies of the master label (one with corrections highlighted) (14 pages ea)
- One CD with Master e-label, 071654.00006.20100412.MasterVirkonS.clarification.pdf

Should you have any questions, please feel free to call me at (302)695-2328 or email susan.m.schaner@usa.dupont.com.

Sincerely,

Susan M. Schaner
Regulatory Coordinator
DuPont Chemicals and Fluoroproducts

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

☐ **Registration**
☒ **Amendment**
☐ **Other: Notification**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6	**Jacqueline McFarlane (acting)**	☒ None ☐ Restricted
4. Company/Product (Name) **Virkon S**	PM# **Team 34**	

5. Name and Address of Applicant *(Include ZIP Code)*
E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
P.O. Box 80402 (E403-3224D)
Wilmington, DE 19880-0402
Attn: Susan M. Schaner

☐ *Check if this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☒ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Virkon S – amendment for clarification language

Non-PRIA Action fast track amendment, no data

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specifiy)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Susan M. Schaner	**Regulatory Coordinator**	**(302) 695-2328**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	
Susan M. Schaner	**Regulatory Coordinator**	
4. Typed Name **Susan M. Schaner**	5. Date 12-Apr-2010	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White- EPA File Copy (original) Yellow- Applicant Copy

71654-6 7/1/2009 1 of 16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUL 1 2009

Bonnie J. Bieber
Regulatory Coordinator
E.I. du Pont de Nemours and Company
DuPont Chemical Solution Enterprise
P.O. Box 80402 (E403-3224D)
Wilmington, DE 19880-0402

Subject: Notification in Accordance with PR Notice 98-10
Virkon® S
EPA Registration No. 71654-6
Application Date: June 3, 2009
Receipt Date: June 8, 2009

Dear Ms. Bieber:

This acknowledges receipt of your application, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

Label change due to PR Notice 2007-4

General Comments

Based on a review of the material submitted, the following comments apply:

The notification is acceptable and a copy has been inserted in your file for future reference.

At your next label amendment amendment you must change *Salmonella Choleraesuis* to *Salmonella enterica*.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6415 or email address at: lantz.tracy@epa.gov or Renae Whitaker by telephone at (703) 308-7003 or email at whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Renae L. Whitaker

Tracy Lantz
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Please read instructions on reverse before completing form. Form Approved OMB No. 2070-0060, Approval expires 05-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other: NOTIFICATION

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6	Emily Mitchell	☒ None ☐ Restricted
4. Company/Product (Name)	PM#	
Virkon S	Team 32	

5. Name and Address of Applicant *(Include ZIP Code)*
E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
P.O. Box 80402 (E403-3224D)
Wilmington, DE 19880-0402
Attn: Bonnie J. Bieber

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

"Notification of label change per PR Notice 2007-4.

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.".

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Bonnie J. Bieber	Regulatory Coordinator	(302) 695-1557

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
	Regulatory Coordinator	
4. Typed Name	5. Date	
Bonnie J. Bieber	6/3/09	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White- EPA File Copy (original), Yellow- Applicant Copy

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

June 3, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard)
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: Virkon S
EPA Registration #: 71654-6
Notification of label change per PR Notice 2007-4

Dear Sir or Madam:

In accordance with PR Notice 2007-4, E.I. du Pont de Nemours and Company is notifying the Agency of Storage and Disposal Language label language upgrades for the above referenced product. Attached please find the following documents supporting this notification:

- Application for Pesticide Registration (EPA form 8570-1) – dated 6/3/09
- One copy of the label with changes highlighted

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Please contact me by phone at 302-695-1557 or by email at bonnie.j.bieber@usa.dupont.com if you have any questions.

Sincerely,

Bonnie J. Bieber
Regulatory Coordinator,
E.I. DuPont de Nemours and Company
DuPont Chemical Solutions Enterprise

attachments

Virkon® S
Disinfectant and Virucide

BROAD SPECTRUM DISINIFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] {OPT}

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against
•Viruses
Including Canine Parvovirus [OPT}
•Bacteria
•Fungi

ACTIVE INGREDIENTS:	
Potassium peroxymonosulfate.....	21.41%
Sodium Chloride.....	1.50%
OTHER INGREDIENTS.....	77.09%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See Inside Booklet for Additional Precautions

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6 EPA Est. No. XXXXX-YY-ZZZ

Front Panel Continued

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice.
If on Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice.
If Swallowed:	• Call Poison Control Center or doctor immediately for treatment advice. • Have Person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
HOT LINE NUMBER	
For 24-hour emergency information on this product, call 1-800-3637 (US & Canada) or 1-302-774-1100 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

ANIMAL AND ZOONOTIC PATHOGENS

BACTERIA

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

Not approved in California for use against the following bacteria:
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycoplasma hyopneumonia
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

Not approved in California cont.

Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagropphytes (2%)

Not approved in California for use against the following fungi:
Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

PLANT PATHOGENS
Not approved in California for use against plant pathogens:
Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
Corrosive statement refers to powder only not in use solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT]

Powder

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Quart	*0.15 ounces**	*0.3 ounces*	*0.7 ounces*
1 Gallon	*0.65 ounces**	*1.3 ounces*	*2.7 ounces*
10 Gallons	*6.7 ounces**	*13.4 ounces*	*26.7 ounces*
50 Gallons	*33.4 ounces**	*66.8 ounces*	*133.5 ounces*

Measuring cup provided.

Tablet

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Pint		*1 tablet*	*2 tablets*
1 Quart	*1 tablet**	*2 tablets*	*4 tablets*
1 Gallon	*4 tablets**	*8 tablets*	*16 tablets*

* The 0.5% solution currently is not approved for use in California.

Sachet

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 gallon	-	*1 Sachet*	*2 Sachets*
2 Gallons	*1 Sachet*	*2 Sachets*	*4 Sachets*

* The 0.5% solution is currently not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts) Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori .

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

12 OR 16

SWINE PRODUCTION

CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens;. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

Aerial Disinfection in the Presence of Poultry and Swine – Not approved

Spraying a fine disinfectant mist or fog in premises, even in the presence of poultry and swine can help control and prevent the spread of viruses.

Apply Virkon® S Disinfectant and Virucide at a dilution rate of 1:200 (0.5%) at an application rate of 1 gallon per 430ft^2 of floor space daily. Use a mechanical (cold fogger) or plumbed in misting system designed for water-based applications, with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer to deliver a very fine mist.

Thermal foggers are not recommended as the noise will disturb the birds.

Note: Individuals should avoid entering the building or room while aerial disinfection is in progress. If the building or room must be entered, then the individuals entering must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme.Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4; *Not approved in California for use against the following organisms:* Bacteria of Moraxella bovis and Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not

intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California:*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following ~~disease~~ organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

~~Disease~~ Organism	Dilution rate	Oz./Gal.
PCV2 Virus (PMWS)	1:200	0.7

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is ~~recommended~~ to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

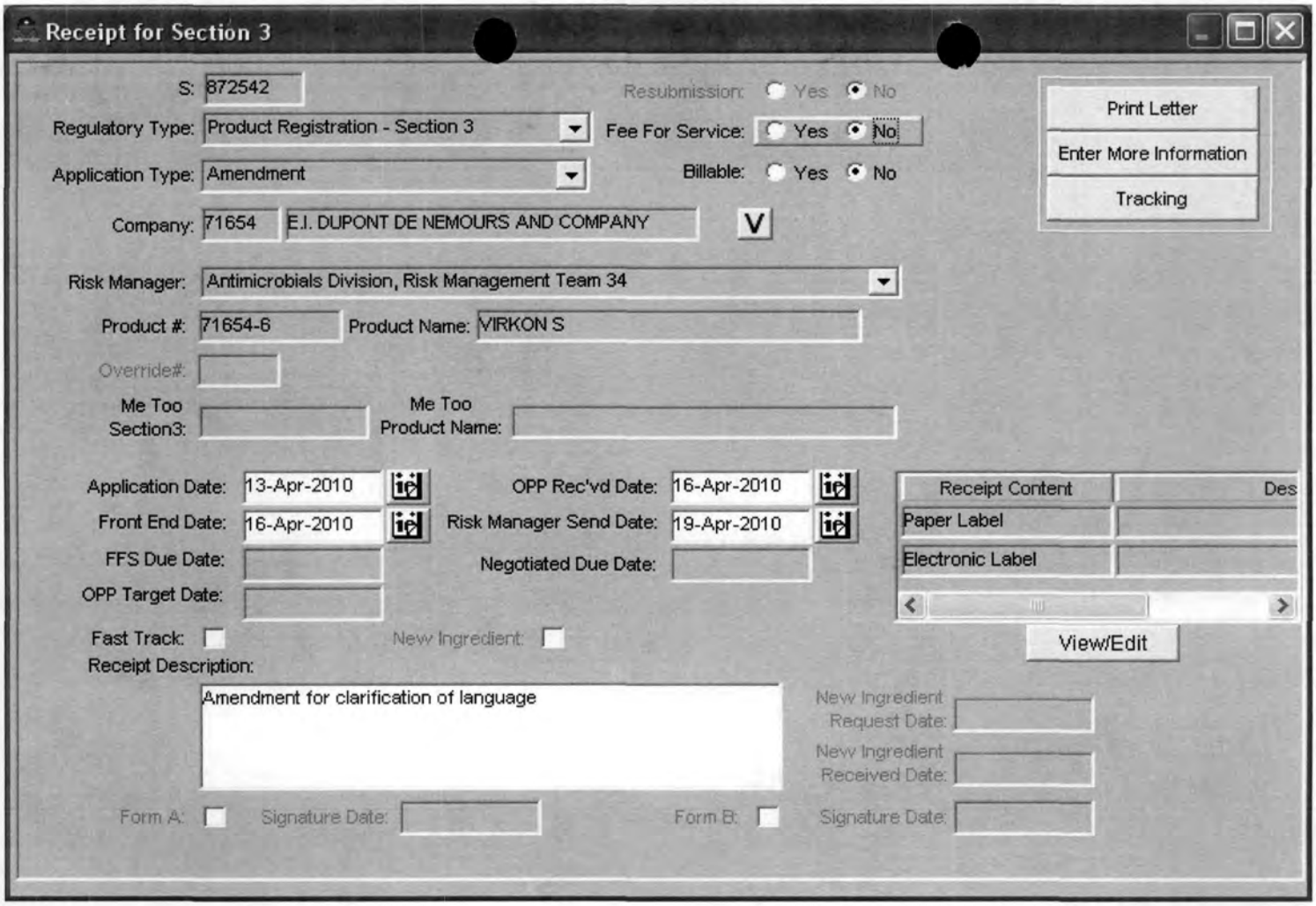
To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

update

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.


Receipt for Section 3
S: 872542
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 71654-6
Product Name: VIRKON S
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 13-Apr-2010
OPP Rec'vd Date: 16-Apr-2010
Front End Date: 16-Apr-2010
Risk Manager Send Date: 19-Apr-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Paper Label
Electronic Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Amendment for clarification of language
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 19, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THOMAS C. MCENTEE
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

PRODUCT NAME: VIRKON S
COMPANY NAME: E.I. DUPONT DE NEMOURS AND COMPANY
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 71654-6
EPA RECEIPT DATE: 04/16/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at (703) 308-6422.

Sincerely,

P. G. Moore
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{872542$~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 34

Receipt No. S-	872542
EPA File Symbol/Reg. No.	71654-6
Pin-Punch Date:	4/16/2010

☑ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Team 1 Date: 4-16-10

Remarks: Please check organisms to make sure they are OK.

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

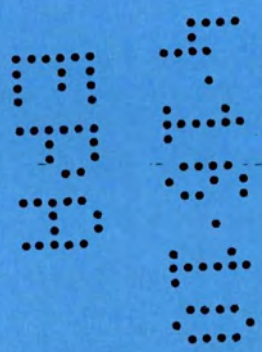
XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.
If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423



PROCESSING ELECTRONIC LABELS

(rev. 1/5/09, tch)

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.

Initial E-Label per application (on CD-ROM with paper via ITRMD)

1 ITRMD receives paper submission w/ e-label on CD

2 Tracking record added to OPPIN

3 ITRMD adds e-label to ELL

4 ITRMD sends paper submission to AD/BPPD/RD

5 Connect ELL record with OPPIN S#

in-process

6 Save copy of e-label from ELL to My Documents

7 Review label
(if acceptable, skip to step 20)

8 Add comments to e-label
(save; add "with comments" to filename

9 Print annotated e-label
(use "Print with Filename")

review

10 Send annotated e-label to registrant via email
(also send "How To Print")

11 File print of annotated e-label and email in jacket

12 Add annotated e-label to ELL

13 Close submission in OPPIN

out-process

Resubmission (via email to staffer or PM)

14 Receive email submission w/ e-label attached

15 Add tracking record to OPPIN

16 Add e-label to ELL

17 Connect ELL record with OPPIN S#

in-process

18 Save copy of e-labels (old & new) from ELL to My Documents

19 Compare old and new labels with Acrobat

(if revisions needed repeat steps 8-19)

review

20 Print e-label, stamp, write cover letter
(use "Print with Filename")

21 Mail stamped label & cover letter to registrant

22 File stamped label & cover letter in jacket

23 Add cover letter to ELL
(mandatory if accepted with comments)

24 Close submission in OPPIN

out-process

process - big picture

1- create OPPIN tracking
2- put label in ELL; link to S#
3- save ELL label to MyDocuments
4- compare / comment
5- outprocess

techniques to know

- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

Material to be added to an e-Jacket/Jacket

Reg. No. 71654-6

1. ☐ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top/newest)
   - ☐ Description: (PDF page number, i.e., "before page 45")

_____

_____

2. ☒ Send to Data Extraction contractors this material:
   - ☐ Newly stamped accepted label
   - ☐ Notification
   - ☒ New CSF ir
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. I must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Lillian Swift

Phone: _____ Division: _____

Date: 7/22/09

Created July 21/2

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager

PRODUCT REVIEWER: Killian Swift	**RMB** II **TEAM** 34
Description of Action: Notification	**EPA File Symbol/Reg No.** 71654-6

Decision No. 409628	**Submission No.** 853237	**Fee for Service Action Code:**
FQPA Action Code: 332	**Non-FQPA Action Code:**	**PRIA FEE AMOUNT: $**

	MONTH	DAY	YEAR
APPLICATION DATE	June	15	2009
EPA PIN DATE	June	24	2009
DATE PM RECEIVED FROM FRONT END	June	29	2009
Date sent to Reviewer	July	1	2009
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			2009
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			**DATE DUE OUT OF AGENCY** July 24, 2009

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/ Residue

COMMENTS:

Killian verify the information regarding to CSF dated March 4, 2005

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

DATE FEE PAID:	**RESPONSE CODE:** 1155 **RESPONSE DATE:** 7/22/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUL 22 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Thomas C. McEntee
E.I. DuPont de Nemours and Company
DuPont Chemical Solutions, P. O. Box 80402
Experimental Station (ESL 402/3442A)
Wilmington, DE 19880-0402

Subject: Notification per PR Notice 98-10
Virkon® S
EPA Registration Number: 71654-6
Application Date: June 15, 2009
Receipt Date: June 24, 2009

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3(c) 9

Proposed Notification:

Update alternate formulation Confidential Statement of Formula.

Comments:

The notification is acceptable. A copy of the alternate formulation CSF, dated 06/15/09, has been inserted in your file for future reference.

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6415 or by e-mail at lantz.tracy@epa.gov or Killian Swift of my staff by telephone at (703) 308-6346 email address at swift.killian@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Tracy Lantz
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

34

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

June 15, 2009

Document Processing Desk
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Ms. Tracy Lantz (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Notification; PR 98-10 V.A.1, 2 or 3

Dear Ms. Lantz

Lisa's letter

This resubmission is in response to your June 2, 2009 letter rejecting updated alternate formulas.

In today's communication I am resubmitting only the alternate formula, "[redacted] **Alternate #2".** This formula is identical to the CSF dated March 4, 2005, which was EPA accepted in June 2005, except that the CAS Registry number is consistent with the CAS number used by NPIRS for PCP Code 063604. [The PC code used in NPIRS for the active ingredient, potassium peroxymonosulfate, is CAS # 10058-23-8.] The formula has not changed, only the CAS number.

Note that the March 4, 2005 CSF differed only from the January 5, 2004 CSF (accepted October 21, 2004) in the reduction of dye from [redacted] with the difference made up with an increase in [redacted] (See also DER Barcode D304905 for EPA Reg. No. 62432-1).

Should you have any questions, feel free to call or e-mail.

Sincerely,

Thomas C. McEntee

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

Inert ingredient information may be entitled to confidential treatment

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6	Tracy Lantz	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Virkon(R) S	34	

5. Name and Address of Applicant *(Include ZIP Code)*

E.I. du Pont de Nemours and Company
Dupont Chemical Solutions Enterprise, P. O. Box 80402
Experimental Station (ESL 402/3442A)
Wilmington, DE 19880-0402

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification for producing locations (Block #2) and country where formulated (Block #6.) Previously accepted alternate formulas.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I furhter understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[X] Yes [X] No	[ ] Yes [ ] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	10 lb., 1lb., 9 oz. , 1.3 oz.	[X]

6. Manner in Which Label is Affixed to Product [X] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas C. McEntee	Product Registration Manager	302 695 6856

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Thomas C. McEntee	Product Registration Manager
4. Typed Name	**5. Date**
Thomas C. McEntee	June 15, 2009

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

2

TRANSMITTAL DOCUMENT

Attention:
Ms. Tracy Lantz
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs
Room S 4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

NAME AND ADDRESS OF SUBMITTER
E.I.du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL402/3224C)
P. O. Box 80023
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

Notification of Alternate Formulation Producing Location per PR Notice 98-10

Resubmission of "Alternate #2" per June 2, 2009 Rejection Letter

"Virkon® S "; EPA Registration No. 71654-6

Transmittal Date: **June 15, 2009**

Transmittal Material:

Volume 1	Administrative Materials	
	-Cover Letter	1 page
	-Application for Pesticide Registration (EPA Form 8570-1)	1 page
	-Transmittal Document	this page
	-CSF Alternate #2 [redacted]	**2 pages**
	-Jan 5, 2005 CSF "Tablet Formula" [62432-1]	2 pages
	- March 4, 2005 CSF "Tablet Formula [redacted] DYE"	2 pages
	- June 7, 2005 EPA letter accepting CSF dated 3/4/05	1 page
	-CSF Check Sheet [Excel totals and % by weight formula]	1 page
	- Substitute Inerts Sourced	1 page

Inert ingredient information may be entitled to confidential treatment

Material to be added to an e-Jacket/Jacket

Reg. No. 7165H-6

1. ☐ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top/newest)
   - ☐ Description: (PDF page number, i.e., "before page 45")

_____

_____

2. ☒ Send to Data Extraction contractors this material:
   - ☐ Newly stamped accepted label
   - ☒ Notification
   - ☐ New CSF
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Renae Whitaker

Phone: _____ Division: AD

Date: 7/1/09

Created July 21/200

RISK ASSIGNMENT FOR
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager

PRODUCT REVIEWER:	Renae Whitaker	RMB II	TEAM 34
Description of Action:	Notification	EPA File Symbol/Reg No.	71654-6
Decision No 414996	Submission No. 851619	Fee for Service Action Code:	
FQPA Action Code: 332	Non-FQPA Action Code:	PRIA FEE AMOUNT: $	

	MONTH	DAY	YEAR
APPLICATION DATE	06	03	2009
EPA PIN DATE	06	08	2009
DATE PM RECEIVED FROM FRONT END			2009
Date sent to Reviewer			2009
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			2009
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			DATE DUE OUT OF AGENCY: 7/7/09

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

COMMENTS: Per PR Notice 2007-4

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

DATE FEE PAID:	RESPONSE CODE: 1155 RESPONSE DATE: 7/1/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUL 1 2009

Bonnie J. Bieber
Regulatory Coordinator
E.I. du Pont de Nemours and Company
DuPont Chemical Solution Enterprise
P.O. Box 80402 (E403-3224D)
Wilmington, DE 19880-0402

Subject: Notification in Accordance with PR Notice 98-10
Virkon® S
EPA Registration No. 71654-6
Application Date: June 3, 2009
Receipt Date: June 8, 2009

Dear Ms. Bieber:

This acknowledges receipt of your application, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

Label change due to PR Notice 2007-4

General Comments

Based on a review of the material submitted, the following comments apply:

The notification is acceptable and a copy has been inserted in your file for future reference.

At your next label amendment amendment you must change *Salmonella Choleraesuis* to *Salmonella enterica.*

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6415 or email address at: lantz.tracy@epa.gov or Renae Whitaker by telephone at (703) 308-7003 or email at whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Renae L. Whitaker

Tracy Lantz
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

June 3, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard)
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: Virkon S
EPA Registration #: 71654-6
Notification of label change per PR Notice 2007-4

Dear Sir or Madam:

In accordance with PR Notice 2007-4, E.I. du Pont de Nemours and Company is notifying the Agency of Storage and Disposal Language label language upgrades for the above referenced product. Attached please find the following documents supporting this notification:

- Application for Pesticide Registration (EPA form 8570-1) – dated 6/3/09
- One copy of the label with changes highlighted

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Please contact me by phone at 302-695-1557 or by email at bonnie.j.bieber@usa.dupont.com if you have any questions.

Sincerely,

Bonnie J. Bieber
Regulatory Coordinator,
E.I. DuPont de Nemours and Company
DuPont Chemical Solutions Enterprise

attachments

Please read instructions on reverse before co[illegible]ting form. Form Appro[illegible] OMB No. 2070-0060, Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☒ **Other: NOTIFICATION**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6	**Emily Mitchell**	
4. Company/Product (Name)	PM#	☒ None ☐ Restricted
Virkon S	**Team 32**	

5. Name and Address of Applicant *(Include ZIP Code)*
E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
P.O. Box 80402 (E403-3224D)
Wilmington, DE 19880-0402
Attn: Bonnie J. Bieber

☐ *Check if this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name_____

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

"Notification of label change per PR Notice 2007-4.

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.".

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specifiy)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Bonnie J. Bieber	**Regulatory Coordinator**	**(302) 695-1557**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	
	Regulatory Coordinator	
4. Typed Name	5. Date	
Bonnie J. Bieber	6/2/09	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White- EPA File Copy (original) Yellow- Applicant Copy

NOTIFICATION
Date Reviewed: 7/1/09
Reviewed By: R. Whitaker

Virkon® S

Disinfectant and Virucide

BROAD SPECTRUM DISINIFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] {OPT}

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against
•Viruses
Including Canine Parvovirus [OPT}
•Bacteria
•Fungi

ACTIVE INGREDIENTS:	
Potassium peroxymonosulfate	21.41%
Sodium Chloride	1.50%
OTHER INGREDIENTS	77.09%
TOTAL	100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

See Inside Booklet for Additional Precautions

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6 EPA Est. No. XXXXX-YY-ZZZ

<Lot or batch #>

Front Panel Continued

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice.
If on Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice.
If Swallowed:	• Call Poison Control Center or doctor immediately for treatment advice. • Have Person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
HOT LINE NUMBER	
For 24-hour emergency information on this product, call 1-800-3637 (US & Canada) or 1-302-774-1100 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

ANIMAL AND ZOONOTIC PATHOGENS

BACTERIA

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

Not approved in California for use against the following bacteria:
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycoplasma hyopneumonia
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

Not approved in California cont.

Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagropphytes (2%)

Not approved in California for use against the following fungi:
Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

PLANT PATHOGENS
Not approved in California for use against plant pathogens:
Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

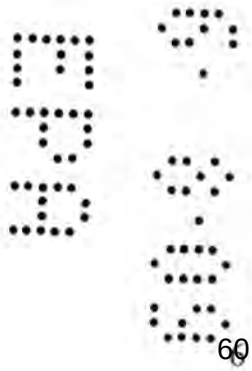
DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
Corrosive statement refers to powder only not in use solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT]

Powder

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Quart	*0.15 ounces**	*0.3 ounces*	*0.7 ounces*
1 Gallon	*0.65 ounces**	*1.3 ounces*	*2.7 ounces*
10 Gallons	*6.7 ounces**	*13.4 ounces*	*26.7 ounces*
50 Gallons	*33.4 ounces**	*66.8 ounces*	*133.5 ounces*

Measuring cup provided.

Tablet

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Pint		*1 tablet*	*2 tablets*
1 Quart	*1 tablet**	*2 tablets*	*4 tablets*
1 Gallon	*4 tablets**	*8 tablets*	*16 tablets*

* The 0.5% solution currently is not approved for use in California.

Sachet

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 gallon	-	*1 Sachet*	*2 Sachets*
2 Gallons	*1 Sachet*	*2 Sachets*	*4 Sachets*

* The 0.5% solution is currently not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts) Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori .

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens;. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme.Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4; *Not approved in California for use against the following organisms:* Bacteria of Moraxella bovis and Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California:*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

Disease Organism	Dilution rate	Oz./Gal.
PCV2 Virus (PMWS)	1:200	0.7

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

PESTICIDE STORAGE Store out of reach of children.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager

PRODUCT REVIEWER: Lisa McKelvin	**RMB** II **TEAM** 34
Description of Action: Notification	**EPA File Symbol/Reg No.** 71654-6
Decision No. 409628	**Submission No.** 849881	**Fee for Service Action Code:**
FQPA Action Code: 332	**Non-FQPA Action Code:**	**PRIA FEE AMOUNT: $**

	MONTH	DAY	YEAR
APPLICATION DATE	5	4	2009
EPA PIN DATE	5	5	2009
DATE PM RECEIVED FROM FRONT END			2009
Date sent to Reviewer			**2009**
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			**2009**
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			**DATE DUE OUT OF AGENCY** 6/4/09

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

COMMENTS: Lisa, Please compare to existing CSFs in the file. If they are the same except for the producing establishment, we can accept.

ATTACHMENTS: ☐-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

DATE FEE PAID:

RESPONSE CODE: 1130 **RESPONSE DATE:** 6/2/09

Inert ingredient information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Thomas C. McEntee
Product Registration Manager
E.I. du Pont de Nemours and Company
Dupont Chemical Solutions Enterprise, P.O. Box 80402
Experimental Station (ESL 402/3442A)
Wilmington, DE 19880-0402

JUN - 2 2009

Subject: Notification Application Per PR Notice 98-10
Virkon® S
EPA Registration No.71654-6
Application Date: May 4, 2009
Receipt Date: May 5, 2009

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification:

Adding new production establishment for alternate formulas.

General Comment:

The notification is not acceptable for the following reasons.

The information supplied for Potassium peroxymonosulfate on Alternate CSFs no.2 and 8 is not in agreement with previously accepted alternate CSFs on file. The CAS# and amount added to the formula does not agree with previous formulations. In addition, please identify a previously accepted CSF which includes the ingredient [redacted].

Alternate formulas #1 through #11 dated May 4, 2009 are not acceptable at this time. Submit revised alternate formulas for review.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6415 or by e-mail at lantz.tracy@epa.gov or Lisa McKelvin by telephone at (703) 308-7496 or by email at mckelvin.lisa@epa.gov .

Sincerely,

Tracy Lantz
(Acting)Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

34

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

May 4, 2009

Document Processing Desk (NOTIF)
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Ms. Tracy Lantz (PM34 - Acting)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Reference: June 6, 2005 Acceptance letter from Mr. Adam Heyward
July 18, 2006 Acceptance letter from Mr. Adam Heyward
January 17, 2007 Acceptance letter from Mr. Adam Heyward

Dear Ms. Lantz,

The purpose of this notification is to clarify the producing establishment addresses and country where manufactured on previously accepted alternate formulas. No new formulations are intended.

Please refer to the attached CSF's for the alternate formulas (#1 thru #11). Also please re-insert the previously approved March 4, 2005 Alternate CSF, "Tablet Formulation ([redacted] dye)" into the file.

None of these alternate formulas are intended to supersede previously accepted basic or alternate formulas.

Thank you for your assistance. Should you have any questions, feel free to call or e-mail.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(978) 312 1136

Inert ingredient information may be entitled to confidential treatment

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6	Tracy Lantz	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Virkon(R) S	34	

5. Name and Address of Applicant *(Include ZIP Code)*

E.I. du Pont de Nemours and Company
Dupont Chemical Solutions Enterprise, P. O. Box 80402
Experimental Station (ESL 402/3442A)
Wilmington, DE 19880-0402

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification for producing locations (Block #2) and country where formulated (Block #6.) Previously accepted alternate formulas.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I furhter understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[X] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	10 lb., 1lb., 9 oz. , 1.3 oz.	[X]

6. *Manner in Which Label is Affixed to Product* [x] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas C. McEntee	Product Registration Manager	302 695 6856

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingllly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Thomas McEntee	Product Registration Manager	Thomas C. McEntee	May 4, 2009

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 17, 2007

Thomas C. McEntee
Product Registration Manager
E.I. du Pont de Nemours and Company
Dupont Chemicals Solutions Enterprise
P.O. Box 80402
Wilimington, DE 19880-0402

Subject: **Virkon®**
EPA Registration No. 71654-7
Letter Dated: January 16, 2007

Dear Mr. McEntee:

This letter is a follow-up to EPA letter dated November 7, 2006 with respect to your submission dated August 18, 2006 concerning the certified limits of the low dye alternate. The Agency evaluated the information provided and in addition to your explanation, and conclude that the certified limits for the low dye alternate is acceptable. Therefore, the alternate confidential statement of formula dated August 17, 2007 is acceptable.

General Comment:

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or by email at heyward.adam@epa.gov or Lisa McKelvin at (703) 308-7496 or by email at mckelvin.lisa@epa.gov.

Sincerely,

Lisa McKelvin

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 18, 2006

Thomas C. McEntee
Product Registration Manager
Dupont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: **Virkon® S**
EPA Registration Number 71654-6
Application: April 17, 2006
Receipt Date: May 18, 2006

Dear Mr. McEntee:

The following amendments, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable.

Proposed Amendment:

- Revised Basic and Alternate Confidential Statement of Formulas (CSF) (See CSFs dated 4-17-06)

General Comment:

A copy of the CSFs has been inserted in your file for future reference. The basic CSF dated April 17, 2006 supersedes all previously accepted basic formulas.

Other Comments:

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@epa.gov, or Renae Whitaker by telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov.

Sincerely,

Renae I. Whitaker

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

June 7, 2005

Thomas C. McEntee
Regulatory Manager
E.I. duPont de Nemours and Company
DuPont Chemical Solutions Enterprise
P.O. Box 80023
Wilmington, DE 19880-0023

Subject: Virkon® S
EPA Registration Number 71654-6
Application Date: March 4, 2005
EPA Received Date: March 10, 2005

Dear Mr. McEntee:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

Proposed Amendment

- Revised Alternate Confidential Statement of Formula (see CSF dated 3/4/05)

General Comments

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

Material to be added to an e-Jacket/Jacket

Reg. No. 71654-6

1. ☐ **Placement within the e-Jacket/jacket:**
   - ☑ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before page 45")**

_____

_____

2. ☒ **Send to Data Extraction contractors this material:**
   - ☑ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Whitaker

Phone: 308-7003 **Division:** AD

Date: 3/3/09

Created July 21/2008

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager

PRODUCT REVIEWER: Renae Whitaker	**RMB** II **TEAM** 34
Description of Action: Label Amendment	**EPA File Symbol/Reg No.** 71654-6
Decision No. 406239	**Submission No.** 844407
Fee for Service Action Code:	
FQPA Action Code: 302	**Non-FQPA Action Code:**
PRIA FEE AMOUNT:	

	DAY	MONTH	YEAR
APPLICATION DATE	05	January	2009
EPA PIN DATE	10	February	2009
DATE PM RECEIVED FROM FRONT END	19	February	2009
Date sent to Reviewer			**2009**
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			**2009**
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			**DATE DUE OUT OF AGENCY**

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

COMMENTS:

USDA/APHIS – Supplemental label without expiration date

ATTACHMENTS: ☑-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

DATE FEE PAID:	**RESPONSE CODE:** 1155 **RESPONSE DATE:** 3/3/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAR - 3 2009

Thomas C. McEntee
Product Registration Manager
E.I. DuPont de Nemours and Company
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: **Virkon (R)S**
EPA Registration No. 71654-6
Application Dated: February 5, 2009
Receipt Date: February 10, 2009

Dear Mr. McEntee:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable.

Proposed Amendment:

Supplemental label – Supersedes original label with Antec International Ltd (EPA. Reg. 62432-1) until label is depleted.

Other comments:

This supplemental label, without an expiration date, supersedes and nullifies the primary container's expiration date.

A stamped copy of the accepted labeling is enclosed.

Thank you for submitting this amendment as an electronic application. Please continue to submit your application(s) electronically. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm.. If you have questions concerning electronic labeling, a list of contacts is available at the above site.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-8583 or email address at: mitchell.emily@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Renae L. Whitaker

Emily Mitchell
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA stamped label

SUPPLEMENTAL LABEL

VIRKON ® S
EPA REG. NO. 71654-6

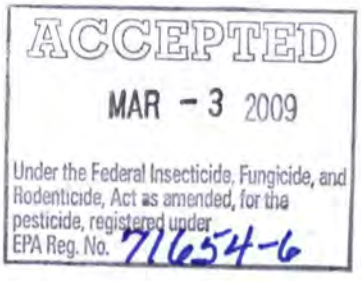
FOR USE BY THE
UNITED STATES DEPARTMENT OF AGRICULTURE
AND USDA'S DESIGNATED COOPERATORS

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

This supplemental label supersedes the primary product label in all regards and must be in the possession of the user at the time of application.

This supplemental label is to be used in lieu of the labels that currently appear on all Virkon® containers in the APHIS Veterinary Services warehouse.

This supplemental label will remain valid until the current stockpile of Virkon S labeled with the Antec International LTD. (EPA Reg. No. 62432-1) label is depleted.



Supplemental Label

Virkon® S
Disinfectant and Virucide

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities

Effective against
•Viruses
•Bacteria
•Fungi

ACTIVE INGREDIENTS:	
Potassium peroxymonosulfate.....	21.41%
Sodium Chloride.....	1.50%
OTHER INGREDIENTS.....	77.09%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See Inside Booklet for Additional Precautions

POWDER FORM

Front Panel Continued

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice.
If on Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice.
If Swallowed:	• Call Poison Control Center or doctor immediately for treatment advice. • Have Person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
HOT LINE NUMBER	
For 24-hour emergency information on this product, call 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

EPA Reg. No. 71654-6 (Originally EPA Reg. No. 62343-1) EPA Est. No. 62432-EN-001

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

ANIMAL AND ZOONOTIC PATHOGENS

BACTERIA

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

Not approved in California for use against the following bacteria:
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycobacterium bovis
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

Not approved in California cont.

Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagropphytes (2%)

Not approved in California for use against the following fungi:
Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

PLANT PATHOGENS
Not approved in California for use against plant pathogens:
Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
Corrosive statement refers to powder only not in use solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

This powder formulation is easily diluted for use in manual or machine operations.

Virkon® S DILUTION CHART
Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water.]

Powder

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Quart	*0.15 ounces**	*0.3 ounces*	*0.7 ounces*
1 Gallon	*0.65 ounces**	*1.3 ounces*	*2.7 ounces*
10 Gallons	*6.7 ounces**	*13.4 ounces*	*26.7 ounces*
50 Gallons	*33.4 ounces**	*66.8 ounces*	*133.5 ounces*

Measuring cup provided.

* The 0.5% solution currently is not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts) Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori .

HATCHERIES: Virkon® S at 2% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 2% solution. Thoroughly wash waterers and feeders with a 2% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-2% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 2% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens;. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 2% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-2% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme.Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 2% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 2% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4; *Not approved in California for use against the following organisms:* Bacteria of Moraxella bovis and Mycobacterium bovis; Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.

Follow General Instructions to remove livestock and preclean area to be treated. A 2% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.

APPLICATIONS: A 2 % solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California:*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 2% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-2% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 2% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 2% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

Disease Organism	Dilution rate	Oz./Gal.
PCV2 Virus (PMWS)	1:200	0.7

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 2% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

February 4, 2009

US Environmental Protection Agency
Office of Pesticide Programs (7504P)
Ms. Emily Mitchell
Antimicrobial Division
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6; Supplemental Label
Request to **Expedite Acceptance on behalf of USDA APHIS**

Dear Ms. Mitchell,

Please refer to the attached documents comprising an application to amend the subject registration to address labeling issues with the current stockpile held by USDA/APHIS in their Kansas City, MO warehouse.

1. Application for Registration-Amendment (8570-1)	1 page
2. e-Label 071654-00006.20090205.VikronS_Supplemental	1 CD
3. Supplemental label Virkon® S	14 pages

This issue has been discussed in detail with both Dr. Nathan Birnbaum DVM, USDA/APHIS and Mr. Jeff Kempter, Senior Advisor US EPA. The action has the support of both Dr. Birnbaum and Mr. Kempter.

USDA/APHIS requested that DuPont initiate this action relative to product in this stockpile that was packaged and labeled with an expiration date of April/May 2006. Based on analytical testing it has been determined that the inventory is still within specification and suitable for its use as a disinfectant and virucide by USDA, including USDA designates. The supplemental label, without an expiration data, supersedes and nullifies the primary container's expiration date.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee / Kdy

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6		[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Virkon (R) S	34	

5. Name and Address of Applicant *(Include ZIP Code)*

E.I. duPont de Nemours and Company
P.O. Box 80402
Wilmington, DE 19880-0402

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Supplemental label - Supercedes label originally applied by registrant Antec International Ltd; EPA Reg. No. 62432-1 at the time of production.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas C. McEntee	Product Registration Mana	978 335 8055

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Thomas C. McEntee / KDG	Product Registration Manager	
4. Typed Name	**5. Date**	
Thomas C. McEntee	Feb 5, 2009	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.
If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423
	Tobi Colvin-Snyder	305-7801

PROCESSING ELECTRONIC LABELS

(rev. 1/5/09, tch)

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.

Initial E-Label per application (on CD-ROM with paper via ITRMD)

[1] ITRMD receives paper submission w/ e-label on CD

[2] Tracking record added to OPPIN

[3] ITRMD adds e-label to ELL

[4] ITRMD sends paper submission to AD/BPPD/RD

[5] Connect ELL record with OPPIN S#

in-process

[6] Save copy of e-label from ELL to My Documents

[7] Review label
(if acceptable, skip to step 20)

[8] Add comments to e-label
(save; add "with comments" to filename

[9] Print annotated e-label
(use "Print with Filename")

review

[10] Send annotated e-label to registrant via email
(also send "How To Print")

[11] File print of annotated e-label and email in jacket

[12] Add annotated e-label to ELL

[13] Close submission in OPPIN

out-process

Resubmission (via email to staffer or PM)

[14] Receive email submission w/ e-label attached

[15] Add tracking record to OPPIN

[16] Add e-label to ELL

[17] Connect ELL record with OPPIN S#

in-process

[18] Save copy of e-labels (old & new) from ELL to My Documents

[19] Compare old and new labels with Acrobat

(if revisions needed repeat steps 8-19)

review

[20] Print e-label, stamp, write cover letter
(use "Print with Filename")

[21] Mail stamped label & cover letter to registrant

[22] File stamped label & cover letter in jacket

[23] Add cover letter to ELL
(mandatory if accepted with comments)

[24] Close submission in OPPIN

out-process

<u>process - big picture</u>

1- create OPPIN tracking
2- put label in ELL; link to S#
3- save ELL label to MyDocuments
4- compare / comment
5- outprocess

<u>techniques to know</u>

- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

MATERIAL TO BE ADDED TO JACKET

REGISTRATION NUMBER: 71654-6

Description: General Email Response

check all that apply		
☐	Final Printed Label Per PR Notice 82-2	Send to CSC
☐	New Basic & Alternate CSFs	
☐	General Letter/Email Response	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's Name: **ADAM HEYWARD**

Date: **29-Jan-2008**

Phone: **703-308-6422**

Division: **Antimicrobials Division**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 29, 2008

Thomas C. McEntee
Product Registration Manager
E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

Subject: Use of Virkon® S with poultry present
Data requirements
EPA Registration No: 71654-6
Application Date: 26-Apr-2007

Dear Mr. McEntee:

The Agency has completed its of the submitted preliminary lab work to support the use of the proposed expansion of the use of Virkon® S (EPA Reg. No. 71654-6) to include treatment of poultry premises without removing the animals. The studies were designed to permit the Agency to guide DuPont as to the nature of any additional residue chemistry data that would be required to support the expanded use. Based on the information provided, the Agency has concluded the following:

An exemption from the requirements of a tolerance is required for residues of the active ingredients "potassium peroxymonosulfate and sodium chloride" when applied to poultry premises in the presence of the animals. Consequently, no additional residue chemistry data are required at this time. A petition requesting this exemption must be submitted to the Agency if you plan to pursue this use formally.

This exemption is based on general knowledge of the chemistry of these compounds as supported by the laboratory studies conducted by DuPont and discussed herein. The persulfate is a very reactive oxidizing agent, is short-lived, and, in/on treated surfaces and livestock, would rapidly be reduced to endogenous sulfate ion in the presence of biomolecules. Any residues that may result in poultry commodities would not be distinguishable from background levels because they are ubiquitous, endogenous inorganic ions common to all living systems.

In association with the proposed amended use and tolerance exemption petition, the Agency has also considered data needs for all other disciplines including occupational/residential exposure, environmental fate, ecological effects, and toxicology. No additional data are necessary for any of these disciplines to support this proposed amended use or petition for an exemption from the requirement of tolerances in eggs; poultry, meat; poultry, fat; and poultry, meat byproducts.

For detailed information and considerations, please refer to the enclosed EPA/AD Risk Assessment and Science Support Branch review dated January 24, 2008.

If you have further questions concerning this letter, please contact me by telephone at 703) 308-6422 or by e-mail at heyward.adam@epa.gov or William J. Hazel, Ph.D., Chemist by telephone at (703) 308-7677 or by email at hazel.william@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: [RASSB Memorandum 1/24/08]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

1/24/08

MEMORANDUM

SUBJECT: **Potassium peroxymonosulfate/sodium chloride.** Use of Virkon® S with poultry present: Data requirements. P.C. Codes 063604 and 013905. EPA Reg. No. 71654-6. D340764.

FROM: William J. Hazel, Ph.D., Chemist
Jenny Tao, Ph.D., Toxicologist
Talia Lindheimer, Occupational Exposure
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

THROUGH: Norman Cook, Branch Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Adam Heyward, RM 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

INTRODUCTION:

DuPont has expressed interest in proposing expansion of the use of Virkon® S (EPA Reg. No. 71654-6) to include treatment of poultry premises without removing the animals. Virkon® S contains potassium peroxymonosulfate at 21.4% and sodium chloride at 1.5%. DuPont has conducted some preliminary lab work at AD's recommendation made at a 3/29/06 meeting. The studies were designed to permit the Agency to guide the registrant as to the nature of any additional residue chemistry data that would be required to support the expanded use.

Note that potassium peroxymonosulfate, also called persulfate, is the active component of a "triple salt" having many applications as an oxidizing agent.

DuPont markets it under the name Oxone®. The triple salt exists in the ratio of two moles of persulfate salt to one mole each of the bisulfate and the sulfate salts, i.e., $2KHSO_5 \bullet KHSO_4 \bullet K_2SO_4$. To improve the antimicrobial properties, sodium chloride is added as a source of halogen. The persulfate component of the triple salt oxidizes the chloride ion of sodium chloride to chlorine, Cl_2. The chlorine then complexes to the amine group of sulfamic acid (added at 4.5% to serve as a chlorine binder/stabilizer) to form the theoretical intermediate N-chlorosulfamic acid. The N-chlorosulfamic acid reacts with water to form hypochlorous acid which reacts with hypochlorite to release oxygen (O_2), HCl, and chloride ion.

The direct treatment of the poultry and failure to rinse the premises after spraying would both typically contribute to a food-use classification unless specific studies are designed which demonstrate that there is no reasonable expectation of residues in poultry commodities resulting from this use. Once a food use classification is made, the next question is whether a tolerance or an exemption from the requirement of a tolerance is appropriate. DuPont and the EPA chemists attending the 3/29/06 meeting had expectations of the chemical products that would likely result at the use site but AD was more concerned with the reaction rates, product ratios, and any potential surprises. The following preliminary investigations were intended to provide this information.

PRELIMINARY EXPERIMENTATION:

The preliminary studies involved simulation of Virkon® S treatment by mixing a 1% aqueous solution on a persulfate salt basis (most common maximum rate) and either maintaining the solution or spraying the solution into empty Petri dishes and monitoring the anionic chemical species over the next 24 hr. Although others were sought, the only anions detected were persulfate (HSO_5^-), bisulfate (HSO_4^-), sulfate (SO_4^{-2}), chloride (Cl^-), sulfamate ($SO_3NH_2^-$), and nitrate (NO_3^-). The sum of the three sulfate anions remained constant (~2750 µg/ml) over the 24-hour period although the three were not distinguishable in the analytical system. The half-life of the persulfate component of Virkon® S dissolved in deionized water was 33 days. Sulfamate remained constant at ~395 µg/ml, chloride declined slightly from 79 to 72 µg/ml, and nitrate increased somewhat from 0.04 to 0.31 µg/ml. N-chlorosulfamic acid, noted above as the suspected first chlorinated intermediate in the oxidation pathway, was not detected.

DISCUSSION/CONCLUSIONS:

An exemption from the requirements of a tolerance appears to be appropriate for residues of potassium peroxymonosulfate and sodium chloride when applied to poultry premises in the presence of the animals. Consequently, no additional

residue chemistry data are required at this time. A petition requesting this exemption must be submitted to the Agency if DuPont plans to pursue this use formally.

This exemption is based on general knowledge of the chemistry of these compounds as supported by the laboratory studies conducted by DuPont and discussed herein. The persulfate is a very reactive oxidizing agent, is short-lived, and, in/on treated surfaces and livestock, would rapidly be reduced to endogenous sulfate ion in the presence of biomolecules. Any residues that may result in poultry commodities would not be distinguishable from background levels because they are ubiquitous, endogenous inorganic ions common to all living systems.

In association with the proposed amended use and tolerance exemption petition, the Agency has also considered data needs for all other disciplines including occupational/residential exposure, environmental fate, ecological effects, and toxicology. No additional data are necessary for any of these disciplines to support this proposed amended use or petition for an exemption from the requirement of tolerances in eggs; poultry, meat; poultry, fat; and poultry, meat byproducts.

Sign-in Sheet
EPA & DuPont
Date: 10/10/07

Name	Phone number & Email Address
William Hazel	703-305-7677 hazel.william@epa.gov
TALIA LINDHEIMER	703-347-8882 lindheimer.talia@epa.gov
Jenny Tao	703-305-7565 Tao.Jenny@epa.gov
Jonathan Chen	703-305-1287 chen.jonathan@epa.gov
Jim Breithaupt	703-305-5925 Breithaupt.James@epa.gov
Siroos Mostaghimi	703-308-8337, Mostaghimi.Siroos@EPA.GOV
Norm Cook	703-308-8253, cook.norm@epa.gov
Tom McEntee	302 695 6856 Thomas.C.McEntee@USA.Dupont.com
~~Adam Heyward~~	
Adam Heyward	703-308-6422 heyward.adam@epa.gov
JEFFREY OBLE	302-695-3461 JEFFREY.A.OBLE@USA.DUPONT.com

USE OF VIRKON® S
Disinfectant and Virucide

Poultry

DuPont - EPA
October 10, 2007

1. Data requirements to **amend** the label - Use in presence of Live Animals. (Ref: DIS/TSS #19)

2. Sub-chronic toxicity to poultry (chicken)

3. Potential Exposure to humans (mixer, loader, applicator) and by-standers

4. Re-Entry to poultry house – Potential for residue build-up on surface

5. Food Residue Consideration

6. PRIA time-frame

BACKGROUND

Oral LD_{50} = 4123 mg/kg
Dermal LD > 2.2 g/kg
Inhalation LC_{50} = 3.7 mg/liter
Irritation = Corrosive to Skin
Use-diluted = Non-irritating

Use of Disinfectant in Presence of Live Poultry and Swine Aquaculture

DuPont – EPA
March 28, 2006

Virkon ® S Disinfectant and Virucide
EPA Reg. No. 71654-6

Cassi Walls	AD/RASSB	703 308 0078
Norm Cook	AD/RASSB	703 308 8253
Adam Heyward	AD RMB II	703 308 6422
Bob Quick	AD/RASSB	703 305 1333
Jenny Tao	AD/RASSB	703 308 7565
Jonathen Chen	AD/RASSB	703 305 1387
Renae Whitaker	AD/RMB Ii	703 308 7003
Tom McEntee	DuPont	302 695 6856

1. Registrant requested the meeting to review registration requirements for amending the label in include disinfection in the presence of animals.

2. EPA does not recognize disinfection of the air, so claim is what falls on horizontal surfaces.

3. Primary issues is what is the nature of the potential residue/potential toxicant. (Suggest studies on the kinetics of persulfate reaction, recovery studies after spraying – what falls onto a petrie plate)

4. EPA considers exposure to animals; air, drinking water, feed, on skin. (Drinking water usually within lines, nipple drinkers)

5. Discuss build-up of residues on inanimate surfaces following several applications.

6. EPA questions exposure to applicators; inhalation studies that support the registration. Dermal exposure to human applicators.

7. Aquaculture use is outside the US, but may require addressing potential tolerances. Primary issue is nature of the residue. Suggest similar study to other DuPont products as in crayfish. May accept bridging data from established chemistry

8. Under PRIA EPA has 15 to 21 months to review application for tolerance or exemption. EPA will accept a request to comment on plan and should be able to respond within 2 to 3 months.

Virkon® S Disinfection in the Presence of Live Poultry and Livestock
Residue Studies

Guideline: USEPA OPPTS 860.1480

Objective: Determine residue levels of sulfamic acid/sulfamate in poultry and swine food items after aerial/fogging disinfection with Virkon® S in the presence of live animals.

Study Design:

Two treatment levels – control and 1x maximum label rate. Treatments will be made twice a week (double what is specified on the label, to present a reasonable worst-case scenario and provide rationale for not conducting 3x and 10x treatments).

Food and water **not** removed.

Poultry: 9 birds per treatment level. At egg collection and sacrifice, samples from groups of 3 birds will be composited to give 3 unique samples per treatment level per sampling event.

Swine: 3 hogs per treatment level. Sample will not be composited.

Study duration: 28 days. Eggs collected on a daily basis and composited to give 3 unique samples per treatment group per day. Sacrifice to be carried out no later than 3 days after the last treatment or according to label directions, whichever duration is shorter.

Samples to be collected at sacrifice: skin, fat, meat, and liver from both hogs and poultry. Poultry samples will be composited as above.

Virkon® S Disinfection in the Presence of Live Poultry and Livestock

Adverse Effects/Toxicology Studies

Guideline: Special Study

Pigs: (One Exposure Group)

Groups:	#1 - Typical exposure	#2 - Worst case
Treatment Frequency	1/day for 120 days	2/day for 120
Concentration	0.5%	2.0%
Dose quantity	1 liter/m3	2 liter/m3
Number of animals/group:	10	10
control group:	10	10

Poultry: (One exposure Group)

Groups:	#1 - Typical exposure	#2 - Worst case
Frequency	1 time/week for 28 days	3 times/week for 45 days
Concentration	0.5%	2.0%
Dose volume	1 liter/m3	2 liter/m3
Number of animals	10	10
control group	10	10

•Clinical observations; including observations of eyes and skin for irritation (daily is preferred, but this could be weekly)

•Routine set of clinical chemistry and coagulation tests on blood collected at end of the study on all animals

•Gross path on all animals

•Tissues, including heart, liver, kidneys, lungs, spleen, brain, and skeletal muscle (from a location that is a source of commercial meat) removed for histology & pathology

•Analytical verification of the test substance in the dosing solutions.

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

TRANSMITTAL FAX

(703) 308 8481

Antimicrobials Division (7510P)
US Environmental Protection Agency
Mr. Adam Heyward (PM34)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

March 20, 2007

Subject: Virkon® S; EPA Registration No. 71654-6
Your letter of March 5, 2007, attached

Dear Mr. Heyward,

Please refer to the attached signed and revised Statement of No Data Confidentiality Claims, page 2 of the study:

Ion Chromatographic and Iodometric Titration Studies of Test Substance H-26820; Powley, Charles R. and Clements, Robert L.; February 15, 2007, E. I. duPont de Nemours and Company.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com (302) 695-6856

STATEMENT OF CONFIDENTIALITY

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section 10(d)(1)(A), (B), or (C).

The statement directly above supersedes and overrides any other statements pertaining to confidentiality which may appear in this study.

E.I. duPont de Nemours and Company

Wilmington, DE 19880-0402

Company Agent: Thomas C. McEntee

Product Registration Manager

[signature] DATE: March 20, 2007

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
03/16/2007 02:38 PM

To Adam Heyward/DC/USEPA/US@EPA
cc
bcc
Subject Follow-Up to Meeting on the use of disinfectant in the presence of Animals; Request for conference; PR98-10 B.6

Mr. Adam Heyward,

This is to request a follow-up meeting to our March 2006 meeting on the same topic.

I have recently submitted new qualitative anlaytical studies and now wish to confirm the details of a combined toxicology/residue study. A key goal of the meeting is to determine whether these would be the final data requirements.

Please refer to the attached DRAFT.

(See attached file: 20070227(A) Virkon(R) S In the presence of live Poultry & Swine .doc)

On a second topic I would like to confirm requirements for adding non-human health organism to the virkon(R) S label.

(See attached file: 20070308 Diseases Notifiable to the OIE.htm)

(See attached file: 20070316 Hydrolyses Virkon Powley DuPont-22200.doc)

Please let me know of any possible dates.

Tom McEntee
302 695 6856
978 335 8055 CELL


20070227(A) Virkon(R) S In the presence of live Poultry & Swine .doc


20070308 Diseases Notifiable to the OIE.htm


20070316 Hydrolyses Virkon Powley DuPont-22200.doc

Virkon® S Disinfection in the Presence of Live Poultry and Livestock
Residue Studies

Guideline: USEPA OPPTS 860.1480

Objective: Determine residue levels of sulfamic acid/sulfamate in poultry and swine food items after aerial/fogging disinfection with Virkon® S in the presence of live animals.

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Virkon® S Disinfection in the Presence of Live Poultry and Livestock

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Guideline: Special Study

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Groups:	#1 - Typical exposure	#2 - Worst case
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Groups:	#1 - Typical exposure	#2 - Worst case
Frequency	1 time/week for 28 days	3 times/week for 45 days
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Dose volume	1 liter/m3	2 liter/m3
Number of animals	10	10
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•Clinical observations; including observations of eyes and skin for irritation (daily is preferred, but this could be weekly)

•Routine set of clinical chemistry and coagulation tests on blood collected at end of the study on all animals

•Gross path on all animals

•Tissues, including heart, liver, kidneys, lungs, spleen, brain, and skeletal muscle (from a location that is a source of commercial meat) removed for histology & pathology

•Analytical verification of the test substance in the dosing solutions.

Updated: 23/01/2006

OIE Listed diseases

Multiple species diseases

- Anthrax
- Aujeszky's disease
- Bluetongue
- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Echinococcosis/hydatidosis
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- Leptospirosis
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever

Sheep and goat diseases

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis)
- Maedi-visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Peste des petits ruminants
- Salmonellosis (S. abortusovis)
- Scrapie
- Sheep pox and goat pox

Cattle diseases

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine tuberculosis
- Bovine viral diarrhoea
- Contagious bovine pleuropneumonia
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Lumpky skin disease
- Malignant catarrhal fever
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted)

Equine diseases

- African horse sickness
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Eastern)
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Equine rhinopneumonitis
- Equine viral arteritis

- Glanders
- Surra (*Trypanosoma evansi*)
- Venezuelan equine encephalomyelitis

Swine diseases

- African swine fever
- Classical swine fever
- Nipah virus encephalitis
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- Swine vesicular disease
- Transmissible gastroenteritis

Avian diseases

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*M. gallisepticum*)
- Avian mycoplasmosis (*M. synoviae*)
- Duck virus hepatitis
- Fowl cholera
- Fowl typhoid
- Highly pathogenic avian influenza and low pathogenic avian influenza in poultry as per Chapter 2.7.12. of the *Terrestrial Animal Health Code*
- Infectious bursal disease (Gumboro disease)
- Marek's disease
- Newcastle disease
- Pullorum disease
- Turkey rhinotracheitis

Lagomorph diseases

- Myxomatosis
- Rabbit haemorrhagic disease

Bee diseases

- Acarapisosis of honey bees
- American foulbrood of honey bees
- European foulbrood of honey bees
- Small hive beetle infestation (*Aethina tumida*)
- *Tropilaelaps* infestation of honey bees
- Varroosis of honey bees

Fish diseases

- Epizootic haematopoietic necrosis
- Infectious haematopoietic necrosis
- Spring viraemia of carp
- Viral haemorrhagic septicaemia
- Infectious pancreatic necrosis
- Infectious salmon anaemia
- Epizootic ulcerative syndrome
- Bacterial kidney disease (*Renibacterium salmoninarum*)
- Gyrodactylosis (*Gyrodactylus salaris*)
- Red sea bream iridoviral disease

Mollusc diseases

- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- Infection with *Mikrocytos mackini*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with *Xenohaliotis californiensis*

Crustacean diseases

- Taura syndrome
- White spot disease
- Yellowhead disease
- Tetrahedral baculovirosis (*Baculovirus penaei*)
- Spherical baculovirosis (*Penaeus monodon*-type baculovirus)
- Infectious hypodermal and haematopoietic necrosis
- Crayfish plague (*Aphanomyces astaci*)

Other diseases

- Camelpox
- Leishmaniosis

Contact : mailto:information.dept@oie.int

Study Title

ION CHROMATOGRAPHIC AND IODOMETRIC TITRATION STUDIES OF TEST SUBSTANCE H-26820

Authors

Charles R. Powley, Ph.D.
Robert L. Clements

Date Study Completed

February 15, 2007

Performing Laboratories

E.I. du Pont de Nemours and Company
DuPont Haskell Laboratory for Health and Environmental Sciences
Stine-Haskell Research Center
Newark, Delaware 19714-0050

E.I. du Pont de Nemours and Company
Corporate Center for Analytical Sciences
Experimental Station
Wilmington, Delaware 19880-0228

Case Consulting Laboratories, Inc.
622 Route Ten
Whippany, NJ 07981

Laboratory Project ID

DuPont-22200

Haskell work request 16787 service code 392

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 5, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 26-FEB-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected Study [01]:

* Your Statement of No Data Confidentiality Claims is contradicted by the marking(s) on page(s)_____1_____ of the study. If you do not intend to make Supplemental Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.

DuPor hemical Solutions Enterprise
P. O. B. . 80402
Wilmington, DE 19880-0402

471151-00

DuPont Chemical Solutions Enterprise

Antimicrobials Division (7510P)
US Environmental Protection Agency
Mr. Adam Heyward (PM34)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

February 20, 2007

Subject: Virkon® S; EPA Registration No. 71654-6

Dear Mr. Heyward,

Please consider this letter and its attachments as a follow-up to our March 29, 2006 meeting (minutes attached). Specifically the question arose around the reactive nature of this technology and what actual chemicals may be detected in use-diluted product. It follows that the toxicology of the system and needs for residues are a function of the specific chemicals species that are presented for potential exposure to animals.

The key conclusions from the attached study with respect to item number 3 of the meeting are:

- "The only observed anions in a simulated Virkon® system were consistent with the intentionally added Oxone® triple salt (monopersulfate, bisulfate and sulfate), chloride and sulfamate. The only reaction product observed was nitrate, at trace levels."

- "N-chlorosulfamate could not be observed in this system, but the experimental evidence does not prove it was not formed. It appears that this species is too reactive to measure using an ion chromatographic system."

Returning to the discussion of the subject meeting, it was indicated that EPA would review the analytical evidence and then comment on a plan for additional data development. I would like to request that the attached study be reviewed as the foundation of the analytical approach. Under separate cover I am submitting a plan to propose the testing for both toxicity and residue questions.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com (302) 695-6856

TRANSMITTAL DOCUMENT

Attention:
Mr. Adam Heyward
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs
2777 South Crystal Drive
Arlington, VA 22202-4501

NAME AND ADDRESS OF SUBMITTER
DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-
Follow-up to Pre-Registration Conference of March 29, 2006

Use-Diluted Product Applied in the Presence of Live Poultry or Swine

"Virkon® S"; EPA Registration No. 71654-6

Transmittal Date: **February 20, 2007**

Transmittal Material:

Volume 1	Administrative Materials	
	-Cover Letter	1 page
	-Minutes of Pre-registration Conference March 29, 2006	1 page
Volume 2	Chemistry Data	
47115101	**Ion Chromatographic and Iodometric Titration Studies of Test Substance H-26820;** Powley, Charles R. and Clements, Robert L.; OPPTS Special Study, E.I. duPont de Nemours and Company and Case Consulting Laboratories Inc., February 15, 2007.	27 pages

Use of Disinfectant in Presence of Live Poultry and Swine
Aquaculture

DuPont – EPA
Minutes March 28, 2006 Meeting

Virkon ® S Disinfectant and Virucide
EPA Reg. No. 71654-6
Attendees

Cassi Walls	AD/RASSB	703 308 0078
Norm Cook	AD/RASSB	703 308 8253
Adam Heyward	AD RMB II	703 308 6422
Bob Quick	AD/RASSB	703 305 1333
Jenny Tao	AD/RASSB	703 308 7565
Jonathen Chen	AD/RASSB	703 305 1387
Renae Whitaker	AD/RMB Ii	703 308 7003
Tom McEntee	DuPont	302 695 6856

1. Registrant requested the meeting to review registration requirements for amending the label in include disinfection in the presence of animals.

2. EPA does not recognize disinfection of the air, so claim is what falls on horizontal surfaces.

3. Primary issues is what is the nature of the potential residue/potential toxicant. (Suggest studies on the kinetics of persulfate reaction, recovery studies after spraying – what falls onto a petrie plate)

4. EPA considers exposure to animals; air, drinking water, feed, on skin. (Drinking water usually within lines, nipple drinkers)

5. Discuss build-up of residues on inanimate surfaces following several applications.

6. EPA questions exposure to applicators; inhalation studies that support the registration. Dermal exposure to human applicators.

7. Aquaculture use is outside the US, but may require addressing potential tolerances. Primary issue is nature of the residue. Suggest similar study to other DuPont products as in crayfish. May accept bridging data from established chemistry

8. Under PRIA EPA has 15 to 21 months to review application for tolerance or exemption. EPA will accept a request to comment on plan and should be able to respond within 2 to 3 months.

Please Read All Instructions Before Completing this Form *(Form must be typed)* Form Approved. OMB No. 2070-0044. Approval Expires 1-31-98

Print Form

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number
71654-6	3134

Note: Do not submit distributor product labels

Name of Registered Product *(basic product name accepted by EPA)*	Distributor Product Name
Virkon S	trifectant Broad Spectrum Disinfrctant Tablets

Name and Address of Distributor *(Type; include ZIP code)*

Vetoquinol USA Inc.
101 Lincoln Avenue
Buena, NJ 08310

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...","distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor: ERIC J. LINN DVM, MPH Director Regulatory Compliance

Date: 31 July 07

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant: Prod Reg. Mgr.

Date: Aug 1, 2007

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete. White - EPA

DATA PACKAGE BEAN SHEET

Date: 08-Jun-2007

Decision #: 379863
DP #: (340446)
NON PRIA
Parent DP#:

FQPA

COPY FOR YOUR INFORMATION

* * * Registration Information * * *

Registration: 71654-6 -

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 34 - Adam Heyward - (703) 308-6422 Room# PY1 S-8238

Risk Manager Reviewer: Adam Heyward AHEYWARD

Sent Date: 26-Apr-2007 Calculated Due Date: 24-Aug-2007 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (307) DATA REQUIRED;TECHNICAL;

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxymonosulfate(20.4%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 08-Jun-2007 Due Back:

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxymonosulfate

DP Title:

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	AD / RASSB			Last Possible Science Due Date: 06-May-2007
Team Name:				Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

RASSB: Attached for your review, minutes of a meeting with Du Pont held on March 28, 2007 and supporting data (471161-01) for disinfection in the presence of animals.

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A

PRODUCT REVIEWER: Adam Heyward	RMB II TEAM 34
Description of Action:	EPA File Symbol/Reg No. 71654-1

Decision No. 379863	Submission No. 809285	Fee for Service Action Code:
FQPA Action Code: 307	Non-FQPA Action Code:	PRIA FEE AMOUNT:

	DAY	MONTH	YEAR
APPLICATION DATE	23	April	2007
EPA PIN DATE	01	May	2007
DATE PM RECEIVED FROM FRONT END	06	June	2007
DATE SENT TO SCIENCE (VIVIAN COMPLETES)			
DATE DUE FROM SCIENCE			2007
FQPA DUE DATE			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology XXXXXX	RASSB Exposure /Residue

Comments:
Attached for your review, minutes of a meeting with Du Pont held on March 28, 2007 and supporting data for disinfection in the presence of animals.

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B For Arctic Slope Contract Only

Contract No.: 0052 | *ARCTIC SLOPE*/MANAGER

Final Task: Signature _____ _____ (Total hrs)

C Reviewer Comments:

DATE FEE PAID: | RESPONSE CODE: | RESPONSE DATE:

S [redacted] 9285

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

Antimicrobials Division (7504P)
US Environmental Protection Agency
Mr. Adam Heyward (PM34)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

April 23, 2007

Subject: **Virkon® S**; EPA Registration No. 71654-6

Dear Mr. Heyward,

This letter is a follow-up to my February 20, 2007 letter (copy attached) and EPA's March 5, 2007 rejection based on 86-5 criteria of the contained study. I have tried to correct the deficiency by fax, but I have not received confirmation or a complete MRID number. Therefore I am re-submitting a corrected version.

I am also still awaiting confirmation of a pre-registration meeting, which has been indicated could occur in May. I look forward to your suggestion of specific dates.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 5, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 26-FEB-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

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* Your Statement of No Data Confidentiality Claims is contradicted by the marking(s) on page(s)_____1_____ of the study. If you do not intend to make Supplemental Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

Antimicrobials Division (7510P)
US Environmental Protection Agency
Mr. Adam Heyward (PM34)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

February 20, 2007

Subject: Virkon® S; EPA Registration No. 71654-6

Dear Mr. Heyward,

Please consider this letter and its attachments as a follow-up to our March 29, 2006 meeting (minutes attached). Specifically the question arose around the reactive nature of this technology and what actual chemicals may be detected in use-diluted product. It follows that the toxicology of the system and needs for residues are a function of the specific chemicals species that are presented for potential exposure to animals.

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TRANSMITTAL DOCUMENT

Attention:
Mr. Adam Heyward
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs
2777 South Crystal Drive
Arlington, VA 22202-4501

NAME AND ADDRESS OF SUBMITTER
DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-
Follow-up to Pre-Registration Conference of March 29, 2006

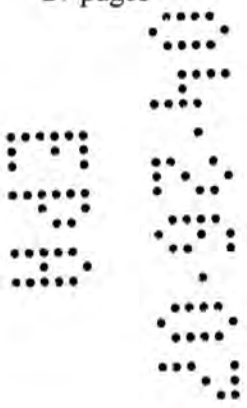
Use-Diluted Product Applied in the Presence of Live Poultry or Swine

"Virkon® S"; EPA Registration No. 71654-6

Transmittal Date: **February 20, 2007**

Transmittal Material:

Volume 1	Administrative Materials	
	-Cover Letter	1 page
	-Minutes of Pre-registration Conference March 29, 2006	1 page
Volume 2	Chemistry Data	
Reject (01)	**Ion Chromatographic and Iodometric Titration Studies of Test Substance H-26820;** Powley, Charles R. and Clements, Robert L.; OPPTS Special Study, E.I. duPont de Nemours and Company and Case Consulting Laboratories Inc., February 15, 2007.	27 pages



DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

470332-00

DuPont Chemical Solutions Enterprise

January 11, 2007

Document Processing Desk -6(a)(2)
Office of Pesticide Programs- 7504C
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Subject: Information Submitted IN Accordance with FIFRA Section 6(a)(2)
Virkon® S; EPA Reg. No. 71654-6
Virkon®; EPA Reg. No. 71654-7
Potassium Peroxymonosulfate; PC Code 063604

47033201 Reference: **Effect of Virkon® Aquatic on the diatoms *Skeletonema costatum* and *Chaetoceros gracilis***; Urtz, Bruce; E.I. du Pont de Nemours and Company; Report No. EMSER 14-06, December 5, 2006, 14 pages.

The attached study was conducted with the EPA registered product Virkon® S, (alternate brand name) to support a use outside of the United States. The study was not conducted in accordance with GLP, nor was it conducted according to OPPTS Guidelines.

This study appears to meet the criteria of 40 CFR 159.165(b)(4) because it may have had an adverse effect on aquatic plants in the test system. Due to the nature of the study its not possible to classify individual plants as affected or non-affected according to the standard of 40 CFR 159.165(b)(4)(i) and (ii).

In summary; after 10 days of exposure to levels of 1.2 ppm Virkon® Aquatic the growth of cultures of *Skeletonema costatum* were inhibited compared to controls. The maximum use rate in the non-US market for Virkon® Aquatic, may be greater than 1.2 ppm, the minimum level which had an effect on plant growth.

Should you have any questions, please feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
302-695-6856

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 5, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 26-FEB-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

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TRANSMITTAL DOCUMENT

Attention:
Mr. Adam Heyward
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs
2777 South Crystal Drive
Arlington, VA 22202-4501

NAME AND ADDRESS OF SUBMITTER
DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-
Follow-up to Pre-Registration Conference of March 29, 2006

Use-Diluted Product Applied in the Presence of Live Poultry or Swine

"Virkon® S"; EPA Registration No. 71654-6

Transmittal Date: **February 20, 2007**

Transmittal Material:

Volume 1 Administrative Materials

-Cover Letter	1 page
-Minutes of Pre-registration Conference March 29, 2006	1 page

Volume 2 Chemistry Data

Reject (01)	**Ion Chromatographic and Iodometric Titration Studies of Test Substance H-26820;** Powley, Charles R. and Clements, Robert L.; OPPTS Special Study, E.I. duPont de Nemours and Company and Case Consulting Laboratories Inc., February 15, 2007.	27 pages

Use of Disinfectant in Presence of Live Poultry and Swine
Aquaculture

DuPont – EPA
Minutes March 28, 2006 Meeting

Virkon ® S Disinfectant and Virucide
EPA Reg. No. 71654-6
Attendees

Cassi Walls	AD/RASSB	703 308 0078
Norm Cook	AD/RASSB	703 308 8253
Adam Heyward	AD RMB II	703 308 6422
Bob Quick	AD/RASSB	703 305 1333
Jenny Tao	AD/RASSB	703 308 7565
Jonathen Chen	AD/RASSB	703 305 1387
Renae Whitaker	AD/RMB Ii	703 308 7003
Tom McEntee	DuPont	302 695 6856

1. Registrant requested the meeting to review registration requirements for amending the label in include disinfection in the presence of animals.

2. EPA does not recognize disinfection of the air, so claim is what falls on horizontal surfaces.

3. Primary issues is what is the nature of the potential residue/potential toxicant. (Suggest studies on the kinetics of persulfate reaction, recovery studies after spraying – what falls onto a petrie plate)

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8. Under PRIA EPA has 15 to 21 months to review application for tolerance or exemption. EPA will accept a request to comment on plan and should be able to respond within 2 to 3 months.

DuPont Chemical Solutions Enterprise
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DuPont Chemical Solutions Enterprise

Antimicrobials Division (7510P)
US Environmental Protection Agency
Mr. Adam Heyward (PM34)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

February 20, 2007

Subject: Virkon® S; EPA Registration No. 71654-6

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Sincerely,

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Thomas.C.McEntee@usa.dupont.com (302) 695-6856

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

TRANSMITTAL FAX
(703) 308 8481

March 20, 2007

Antimicrobials Division (7510P)
US Environmental Protection Agency
Mr. Adam Heyward (PM34)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Your letter of March 5, 2007, attached

Dear Mr. Heyward,

Please refer to the attached signed and revised Statement of No Data Confidentiality Claims, page 2 of the study:

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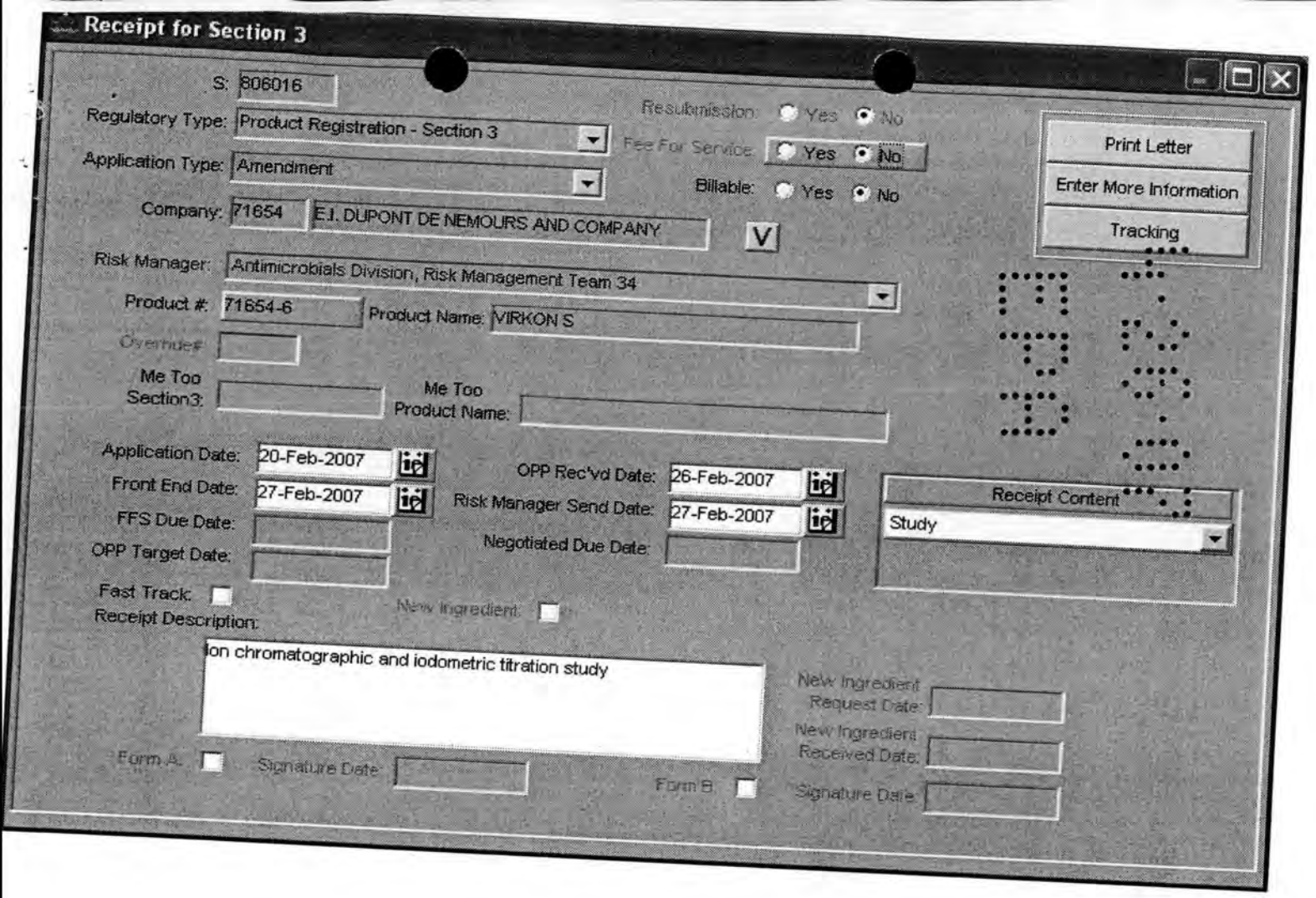
Receipt for Section 3
S: 806016
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 71654-6
Product Name: VIRKON S
Override:
Me Too Section3:
Me Too Product Name:
Application Date: 20-Feb-2007
Front End Date: 27-Feb-2007
FFS Due Date:
OPP Target Date:
Fast Track:
Receipt Description:
ion chromatographic and iodometric titration study
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
OPP Rec'vd Date: 26-Feb-2007
Risk Manager Send Date: 27-Feb-2007
Negotiated Due Date:
Receipt Content
Study
New Ingredient:
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 5, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

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DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

Antimicrobials Division (7510P)
US Environmental Protection Agency
Mr. Adam Heyward (PM34)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

February 20, 2007

Subject: Virkon® S; EPA Registration No. 71654-6

Dear Mr. Heyward,

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TRANSMITTAL DOCUMENT

Attention:
Mr. Adam Heyward
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs
2777 South Crystal Drive
Arlington, VA 22202-4501

NAME AND ADDRESS OF SUBMITTER
DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-
Follow-up to Pre-Registration Conference of March 29, 2006

Use-Diluted Product Applied in the Presence of Live Poultry or Swine

"Virkon® S"; EPA Registration No. 71654-6

Transmittal Date: **February 20, 2007**

Transmittal Material:

Volume 1 Administrative Materials

-Cover Letter	1 page
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Use of Disinfectant in Presence of Live Poultry and Swine
Aquaculture

DuPont – EPA
Minutes March 28, 2006 Meeting

Virkon ® S Disinfectant and Virucide
EPA Reg. No. 71654-6
Attendees

Cassi Walls	AD/RASSB	703 308 0078
Norm Cook	AD/RASSB	703 308 8253
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Use of Disinfectant in Presence of Live Poultry and Swine
Aquaculture

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 30, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

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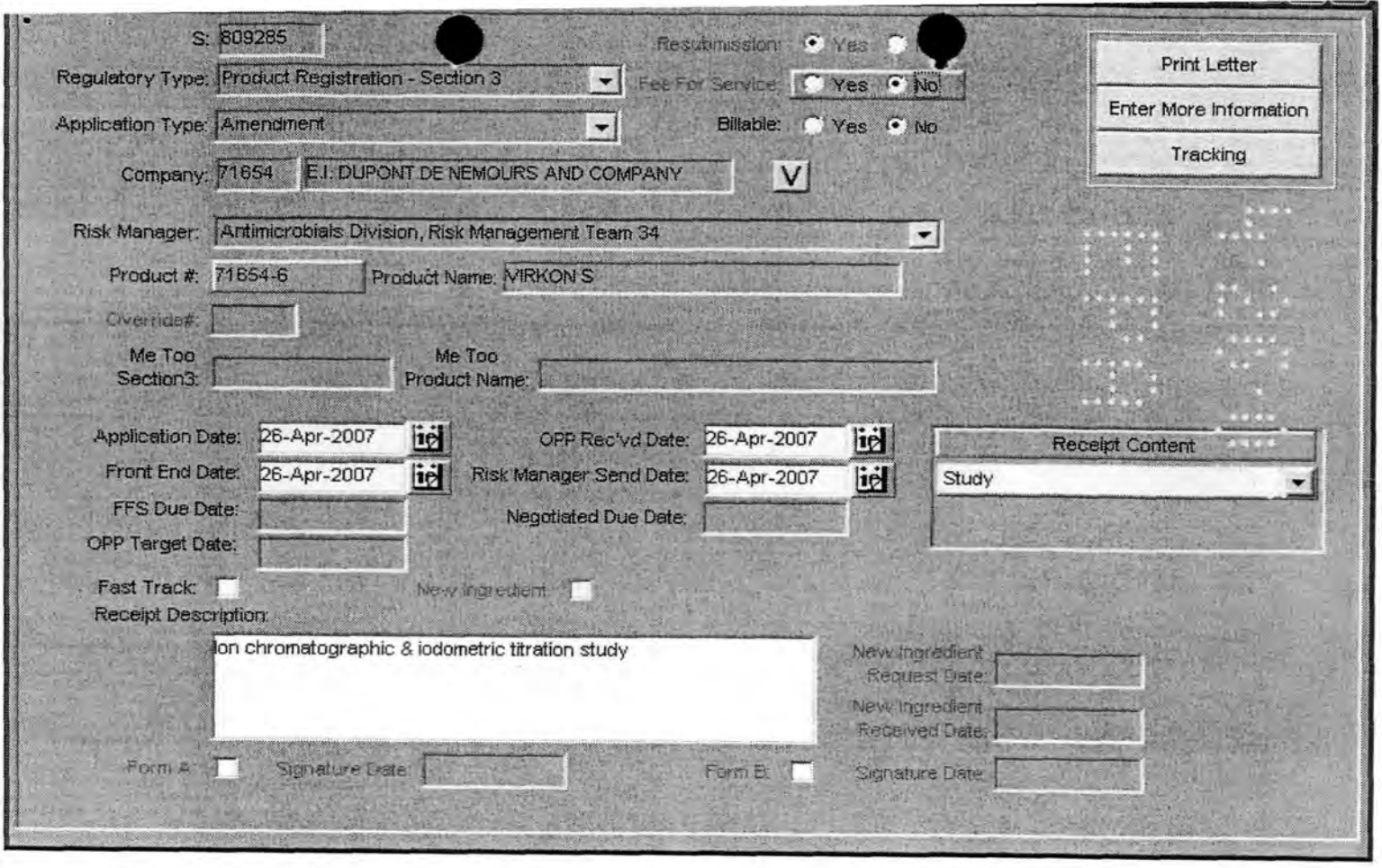
Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


S: 809285
Resubmission: Yes
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 71654-6
Product Name: VIRKON S
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 26-Apr-2007
OPP Rec'vd Date: 26-Apr-2007
Front End Date: 26-Apr-2007
Risk Manager Send Date: 26-Apr-2007
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
Fast Track:
New Ingredient:
Receipt Description:
ion chromatographic & iodometric titration study
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

DuPont [redacted]mical Solutions Enterprise
P. O. Box [redacted]0402
Wilmington, DE 19880-0402

471151-00

DuPont Chemical Solutions Enterprise

Antimicrobials Division (7510P)
US Environmental Protection Agency
Mr. Adam Heyward (PM34)
Room S-4900, One Potomac Yard
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Arlington, VA 22202-4501

February 20, 2007

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	-Minutes of Pre-registration Conference March 29, 2006	1 page
Volume 2	Chemistry Data	
47115101	**Ion Chromatographic and Iodometric Titration Studies of Test Substance H-26820;** Powley, Charles R. and Clements, Robert L.; OPPTS Special Study, E.I. duPont de Nemours and Company and Case Consulting Laboratories Inc., February 15, 2007.	27 pages

MATERIAL TO BE ADDED TO JACKET

REG # 71654-6

Description: Revised labeling

check all that apply		
☐	new stamped accepted label	Send to CSC
☐	new CSF	
☒	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's Name: Stacey Grigsby Date: 8/9/07

Phone: 305-6440 Division: AD

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A

PRODUCT REVIEWER: Stacey Grigsby	RMB II TEAM 34
Description of Action:	EPA File Symbol/Reg No. 71654-6

Decision No. 382063	Submission No. 814374	Fee for Service Action Code:
FQPA Action Code: 332	Non-FQPA Action Code:	PRIA FEE AMOUNT:

	DAY	MONTH	YEAR
APPLICATION DATE	23	July	2007
EPA PIN DATE	26	July	2007
DATE RISK MANAGER RECEIVED FROM FRONT END	27	July	2007
DATE SENT TO SCIENCE (VIVIAN COMPLETES)			2007
PM DUE DATE			2007
NEGOTIATED DUE DATE			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

Comments:

Check to ensure that "Mycoplasma hyopneumonia" is not a public health organism. Based on registrant explanation, the sachet dilution chart can be added to the label.

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B	For Arctic Slope Contract Only	
	Contract No.: 0052	*ARCTIC SLOPE*/MANAGER
	Final Task: Signature _____	_____ (Total hrs)
C	Reviewer Comments:	

DATE FEE PAID:	RESPONSE CODE: 1/55 RESPONSE DATE: 8/9/07

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 9, 2007

Thomas McEntee
E.I DuPont de Nemours and Company
Dupont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: **Virkon (R) S**
EPA Registration No.: 71654-6
Application Date: July 23, 2007
Receipt Date: July 26, 2007

Dear Mr. McEntee:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c) 9.

Proposed Notification:

- Adding the Pest: Mycoplasm hypopneumonia

General Comment:

Based on a review of the material submitted, the following comment applies:

A copy of the accepted notification has been added to your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Stacey Grigsby at (703) 305-6440.

Sincerely,

Stacey Grigsby

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

July 23, 2007

Document Processing Desk
Antimicrobials Division (7504P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Mr. Adam Heyward (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Notification: Addition of the pest, *Mycoplasma hyopneumonia*
Resubmission of Label with Water-soluble Sachet

Dear Mr. Heyward,

Please consider the following in support of NOTIFICATION for the subject registration.

1. Application Form 8570-1 — 1 page
2. Revised Labeling (5 copies) adding *Mycoplasma hyopneumonia* — 13 pages
   - •Mycoplasm hyopneumona – Page 3 line 10
   - •Addition of Sachet Dilution Chart – Page 8 Lines 1-6

As expressed in my June 12 e-mail, the "sachet" is a pre-measured water-soluble unit dose pack. The Sachet was expressed on the November 19, 2004 stamped-accepted label. Sachet directions substantially similar to those of the present application are currently approved for the sister product Virkon®; EPA Registration No. 71654-7. The Sachet is not designed to exert any effect in the room air.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6	Adam Heyward	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Virkon (R) S	34	

5. Name and Address of Applicant *(Include ZIP Code)*

E.I. du Pont de Nemours and Company
Attn: Thomas C. McEntee
Dupont Chemical Solutions Enterprise, P. O. Box 80402
Wilmington, DE 19880-0402

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.

[X] Resubmission in response to Agency letter dated May 29, 2007

[X] Notification - Explain below.

[ ] Final printed labels in repsonse to Agency letter dated _____

[ ] "Me Too" Application.

[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification Addition of the Pest, Mycoplasm hyopneumonia per PR Notice 98-10 II.B. Re-Adding Sachet form and Sachet dilution chart.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I furhter understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[X] Yes [ ] No	[X] Yes [ ] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt: 1.3 oz. / No. per container: 50	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	10 lb., 4 lb, 1lb., 9 oz.,	[X]

6. Manner in Which Label is Affixed to Product [x] Lithograph Paper glued Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas C. McEntee	Product Registration Manager	302 695 6856

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Thomas C. McEntee	Product Registration Manager	Thomas C. McEntee	July 23, 2007

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Virkon® S
Disinfectant and Virucide

BROAD SPECTRUM DISINIFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] {OPT}

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against
•Viruses
Including Canine Parvovirus [OPT}
•Bacteria
•Fungi

ACTIVE INGREDIENTS:	
Potassium peroxymonosulfate.....	21.41%
Sodium Chloride.....	1.50%
OTHER INGREDIENTS.....	77.09%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See Inside Booklet for Additional Precautions

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6 EPA Est. No. XXXXX-YY-ZZZ

Front Panel Continued

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice.
If on Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice.
If Swallowed:	• Call Poison Control Center or doctor immediately for treatment advice. • Have Person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
HOT LINE NUMBER	
For 24-hour emergency information on this product, call 1-800-3637 (US & Canada) or 1-302-774-1100 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

ANIMAL AND ZOONOTIC PATHOGENS

BACTERIA

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

Not approved in California for use against the following bacteria:
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycoplasma hyopneumonia
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

Not approved in California cont.

Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagropphytes (2%)

Not approved in California for use against the following fungi:
Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

PLANT PATHOGENS
Not approved in California for use against plant pathogens:
Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
Corrosive statement refers to powder only not in use solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT]

Powder

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Quart	*0.15 ounces**	*0.3 ounces*	*0.7 ounces*
1 Gallon	*0.65 ounces**	*1.3 ounces*	*2.7 ounces*
10 Gallons	*6.7 ounces**	*13.4 ounces*	*26.7 ounces*
50 Gallons	*33.4 ounces**	*66.8 ounces*	*133.5 ounces*

Measuring cup provided.

Tablet

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Pint		*1 tablet*	*2 tablets*
1 Quart	*1 tablet**	*2 tablets*	*4 tablets*
1 Gallon	*4 tablets**	*8 tablets*	*16 tablets*

* The 0.5% solution currently is not approved for use in California.

Sachet

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 gallon	-	*1 Sachet*	*2 Sachets*
2 Gallons	*1 Sachet*	*2 Sachets*	*4 Sachets*

* The 0.5% solution is currently not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts) Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori .

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens;. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme.Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4; *Not approved in California for use against the following organisms:* Bacteria of Moraxella bovis and Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California:*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

Disease Organism	Dilution rate	Oz./Gal.
PCV2 Virus (PMWS)	1:200	0.7

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

MATERIAL TO BE ADDED TO JACKET

REG # 71654-6

Description: CSFs Unacceptable

check all that apply		
☐	new stamped accepted label	Send to CSC
☒	new CSF	
☐	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's Name: Asker Graham Date: 6/28/07

Phone: 347-8734 Division: AD

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A

PRODUCT REVIEWER: Asher Grahn	**RMB** II **TEAM** 34
Description of Action:	**EPA File Symbol/Reg No.** 71654-6

Decision No. 378176	**Submission No.** 808775	**Fee for Service Action Code:**
FQPA Action Code: 362	**Non-FQPA Action Code:**	**PRIA FEE AMOUNT:**

	DAY	MONTH	YEAR
APPLICATION DATE	03	April	2007
EPA PIN DATE	04	April	2007
DATE PM RECEIVED FROM FRONT END	16	APRIL	2007
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			
DATE RECEIVED FROM SCIENCE			2007
PRIA DUE OUT DATE/Negotiated			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue
	■■■■■						

COMMENTS:

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B For Arctic Slope Contract Only

Contract No.: 0052 ARCTIC SLOPE/MANAGER

Final Task: Signature _____ 3 (Total hrs)

C Reviewer Comments:

DATE FEE PAID:

RESPONSE CODE: 1130 **RESPONSE DATE:** 6/28/07

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

June 28, 2007

Thomas C. McEntee
Product Registration Manager
E.I. du Pont De Nemours and Company
Dupont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: Virkon S
EPA Registration No.: 71654-6
Application Date: April 3, 2007
Receipt Date: April 4, 2007

Dear Mr. McEntee,

The agency has completed its review of the information submitted behalf of your alternate confidential statements of formula (CSFs) and concluded that the amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the reasons below.

General Comments

Based on a review of the material submitted, the following comments apply:

- The CSFs, dated 4/9/2007 for alternate formulations #1-5 are not acceptable. Please see the attached review containing confidential business information for recommendations.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or email at heyward.adam@epa.gov.

Sincerely,

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL	7510P						
SURNAME	Gaylin						
DATE	6/28/07						

EPA Form 1320-1A (1/90) Printed on Recycled P

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

06/18/07

DP BARCODE:	D339075
MRID:	None
SUBJECT:	VIRKON ® S
REG. NO. OR FILE SYMBOL:	71654-6
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]
INGREDIENTS (PC Codes)	Sodium chloride (013905); Potassium peroxymonosulfate (063604)
CAS Number:	(7647-14-5); (10058-23-8)
TEST LAB:	None
SUBMITTER:	E.I. DuPont de Nemours and Company
GUIDELINE:	None
COMMODITIES:	Formulation
REVIEWER:	Juan F. Negrón ORGANIZATION: AD
APPROVER:	Karen P. Hicks APPROVED DATE:
COMMENT:	So Karen P. Hicks June 19, 2007

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

06/18/07

TO:	Adam Heyward / Aster Grahn PM Team 34
FROM:	Juan F. Negrón, Chemist Product Science Branch, CT Team Antimicrobial Division (7510P)
THRU:	Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobial Division (7510C)
THRU:	Michele E. Wingfield, Chief Product Science Branch Antimicrobial Division (7510C)

APPLICANT: E.I. DuPont de Nemours and Company
Action code: 362
Due date: 07/03/07

Product Formulation
Active Ingredient(s)

	% by wt.
Sodium chloride	1.50
Potassium peroxymonosulfate	21.41

BACKGROUND:

The registrant, E.I. DuPont de Nemours and Company, is submitting alternate formulations for review. The integrated end-use product, VIRKON ® S, is used for cleaning and disinfecting industrial, animal and agricultural facilities.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
   - A letter, dated 04/03/07.
   - A label, dated 07/26/06.
   - Application for pesticide, dated 04/03/07, EPA Form 8570-1.
   - Confidential Statements of Formula (CSFs), dated 04/09/07, for alternate # (1 thru 5) formulations.

2. The CSFs, dated 04/09/07, for alternate # (1 thru 5) formulations are revised.

3. The CSFs and the label have the same nominal for alternate # (1, & 2,) formulations.

4. The CSFs and the label do not have the same nominal for alternate # (3, 4, & 5) formulations.

5. See attachment. CBI.

6. See attachment. CBI.

7. See attachment. CBI.

8. See attachment. CBI.

9. See attachment. CBI.

10. See attachment. CBI.

RECOMMENDATIONS:

1. See attachment. CBI.

2. See attachment. CBI.

3. See attachment. CBI.

4. See attachment. CBI.

5. See attachment. CBI.

6. See attachment. CBI.

7. See attachment. CBI.

8. See attachment. CBI.

CONCLUSION:

The CSFs, dated 04/09/07, for alternate # (1 thru 5) formulations are not acceptable. The registrant must comply with the finding and recommendation listed above (See CBI attachment).

CONFIDENTIAL BUSINESS INFORMATION ATTACHMENT
CBI

DP #339075 EPA Reg # 71654-6 VIRKON ® S

FINDINGS:

5. [redacted]
6.
7.
8.
9.
10.

RECOMMENDATIONS:

1. [redacted]
2.
3.

Inert ingredient information may be entitled to confidential treatment

4. [redacted]

5. [redacted]

6. [redacted]

7. [redacted]

8. [redacted]

Inert ingredient information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

Bcc: Mr. Juan Negron
Information on the composition of the [redacted] was submitted directly to you from the manufacturer. Ref. your telephone call Jan. 2007

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

April 3, 2007

Document Processing Desk
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Mr. Adam Heyward (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6

Dear Mr. Heyward,

Please refer to the attached CSF's for the alternate formulas corrected in accordance with your rejection letter of March 14, 2007.

Basic Pink (Alternate #1)
Basic Pink Tablet (Alternate #2)

We cannot change the active declaration for specific alternates. (Reference your letter page 2, comment 1). Note that the stamped-accepted label shows the ingredient statement:

"Sodium chloride … 1.50%".

I am also pleased to submit an additional three alternate formulas.

Thank you for your assistance. Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6	Adam Heyward	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Virkon (R) S	34	

5. Name and Address of Applicant *(Include ZIP Code)*

E.I. du Pont de Nemours and Company
Attn: Thomas C. McEntee
Dupont Chemical Solutions Enterprise, P. O. Box 80402
Wilmington, DE 19880-0402

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Minor formulation Amendment per PR Notice 98-10

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[X] Yes [ ] No	[X] Yes [ ] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt: 1.3 oz. / No. per container: 50	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	10 lb., 4 lb, 1lb., 9 oz.,	[X]

6. Manner in Which Label is Affixed to Product: [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas C. McEntee	Product Registration Manager	302 695 6856

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Thomas C. McEntee	Product Registration Manager	
4. Typed Name	**5. Date**	
Thomas C. McEntee	April 3, 2007	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

TRANSMITTAL DOCUMENT

Attention:
Mr. Adam Heyward
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs
Room S 4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

NAME AND ADDRESS OF SUBMITTER
E.I.du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL402/3224C)
P. O. Box 80023
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

Application for Accelerated Review of Minor Formulation Change per PR Notice 98-10

Resubmission of "Alternate 1 and 2" per March 14, 2007 Rejection Letter
Submission of Alternates 3, 4, and 5

"Virkon® S "; EPA Registration No. 71654-6

Transmittal Date: **April 3, 2007**

Transmittal Material:

Volume 1	Administrative Materials	
	-Cover Letter	1 page
	-Application for Pesticide Registration (EPA Form 8570-1)	1 page
	-Transmittal Document	this page
	[redacted]	
	-Worksheet Component Total to CSF Block 17	1 page

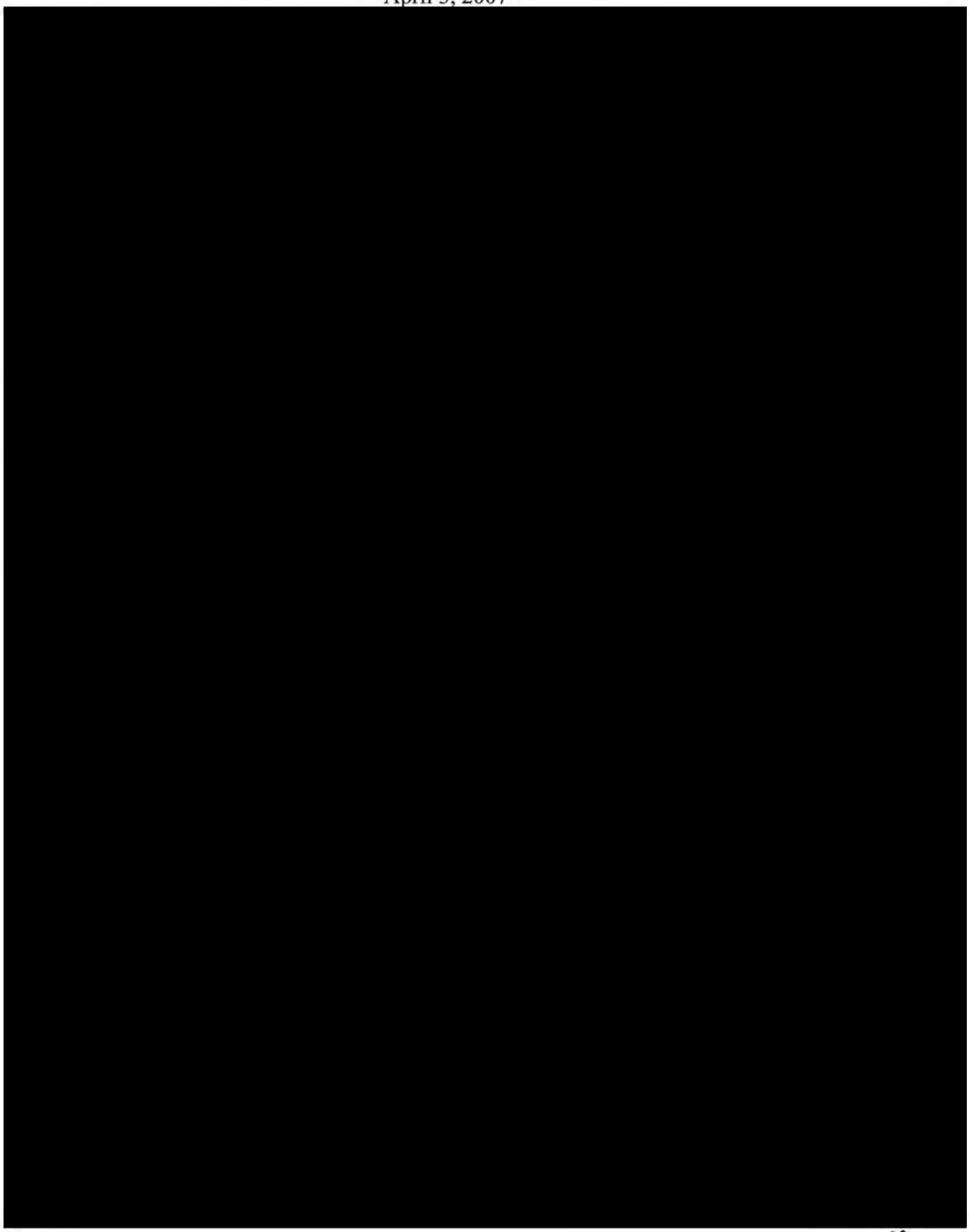
Inert ingredient information may be entitled to confidential treatment

Attachment to Confidential Statements of Formula
EPA Form Number 8570-4
EPA Registration No. 71654-6; Virkon® S
EPA Registration No. 71654-7; Virkon®
April 3, 2007

[redacted]

Inert ingredient information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

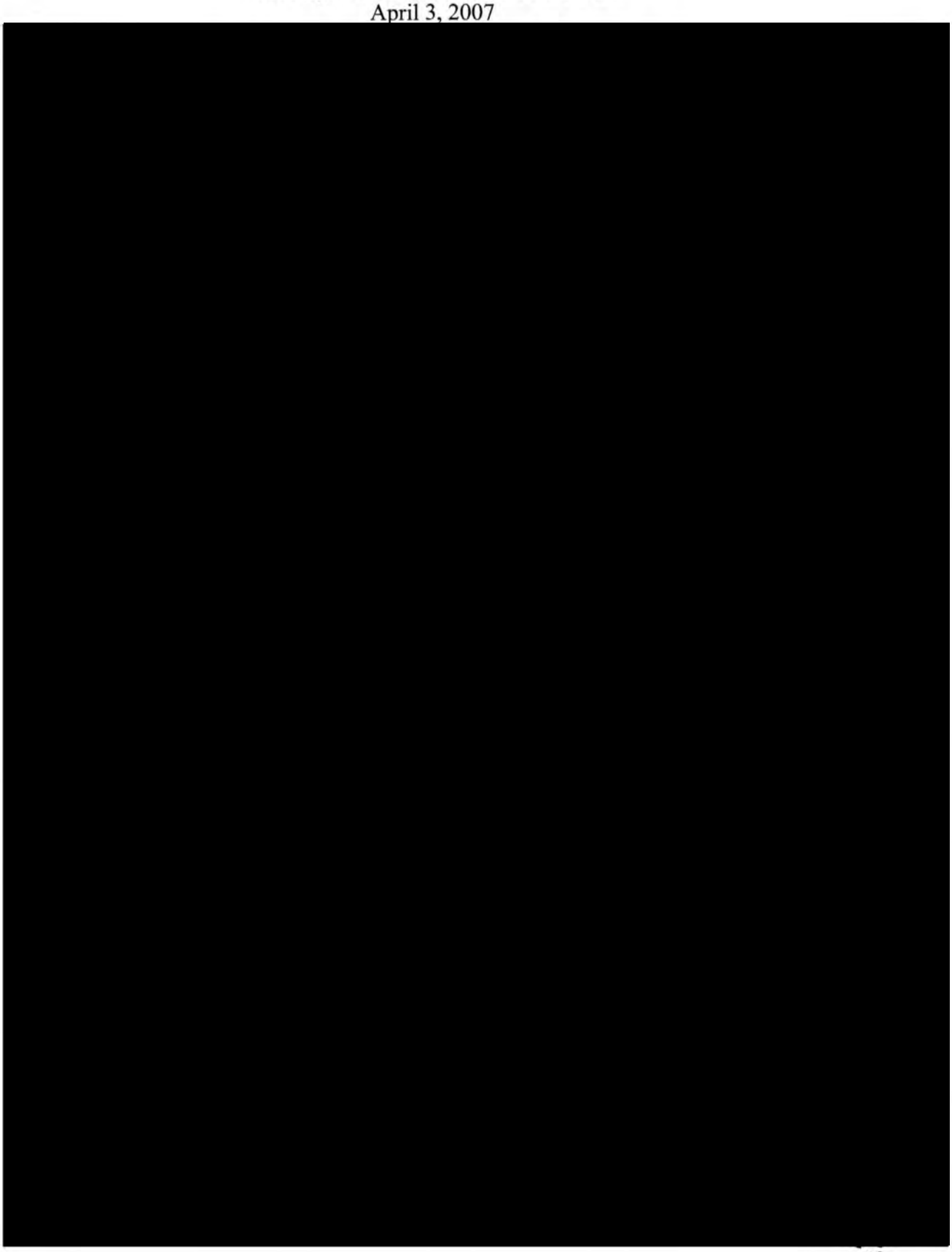
Attachment to Confidential Statements of Formula
EPA Form Number 8570-4
EPA Registration No. 71654-6; Virkon® S
EPA Registration No. 71654-7; Virkon®
April 3, 2007



Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

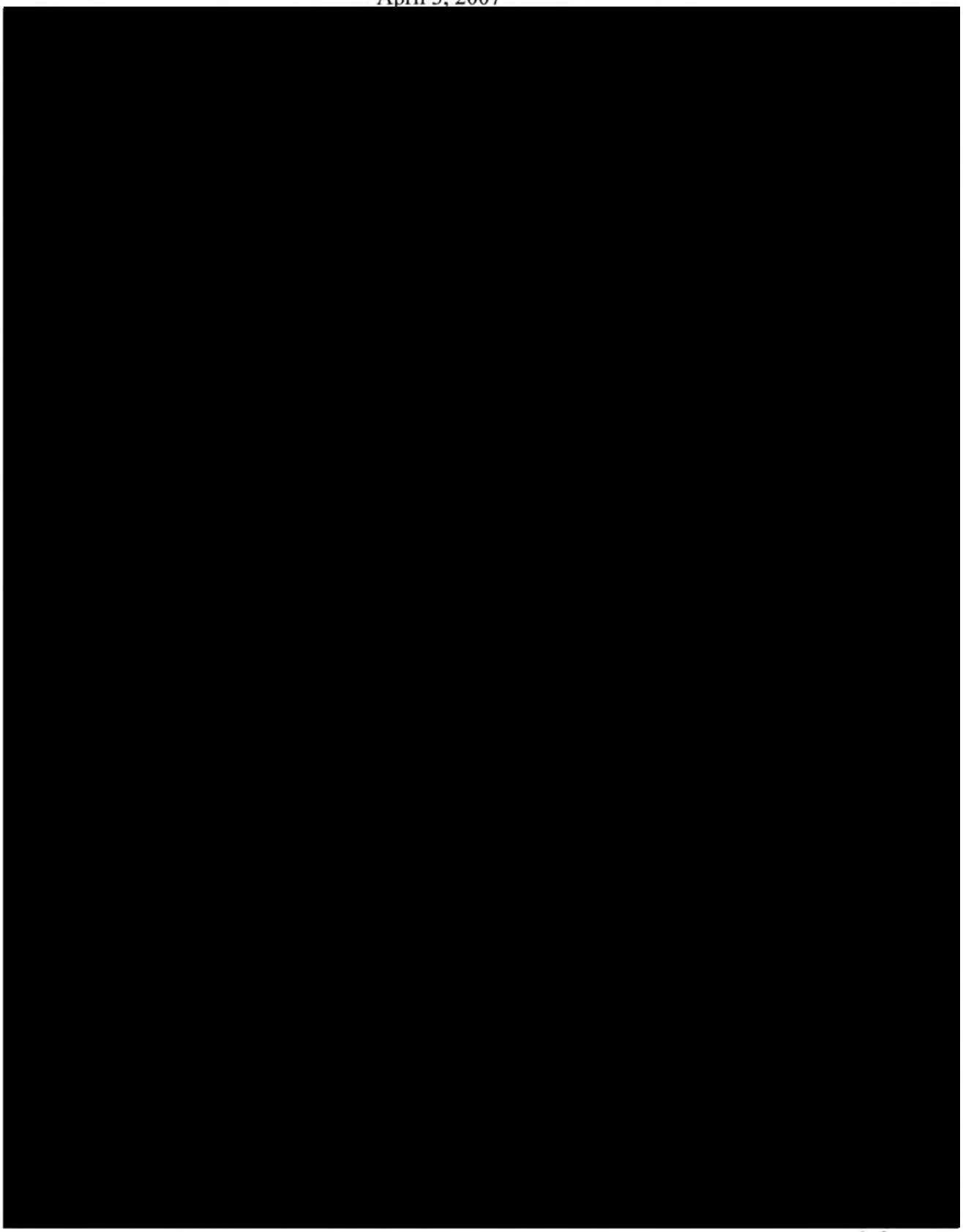
Attachment to Confidential Statements of Formula
EPA Form Number 8570-4
EPA Registration No. 71654-6; Virkon® S
EPA Registration No. 71654-7; Virkon®
April 3, 2007



Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

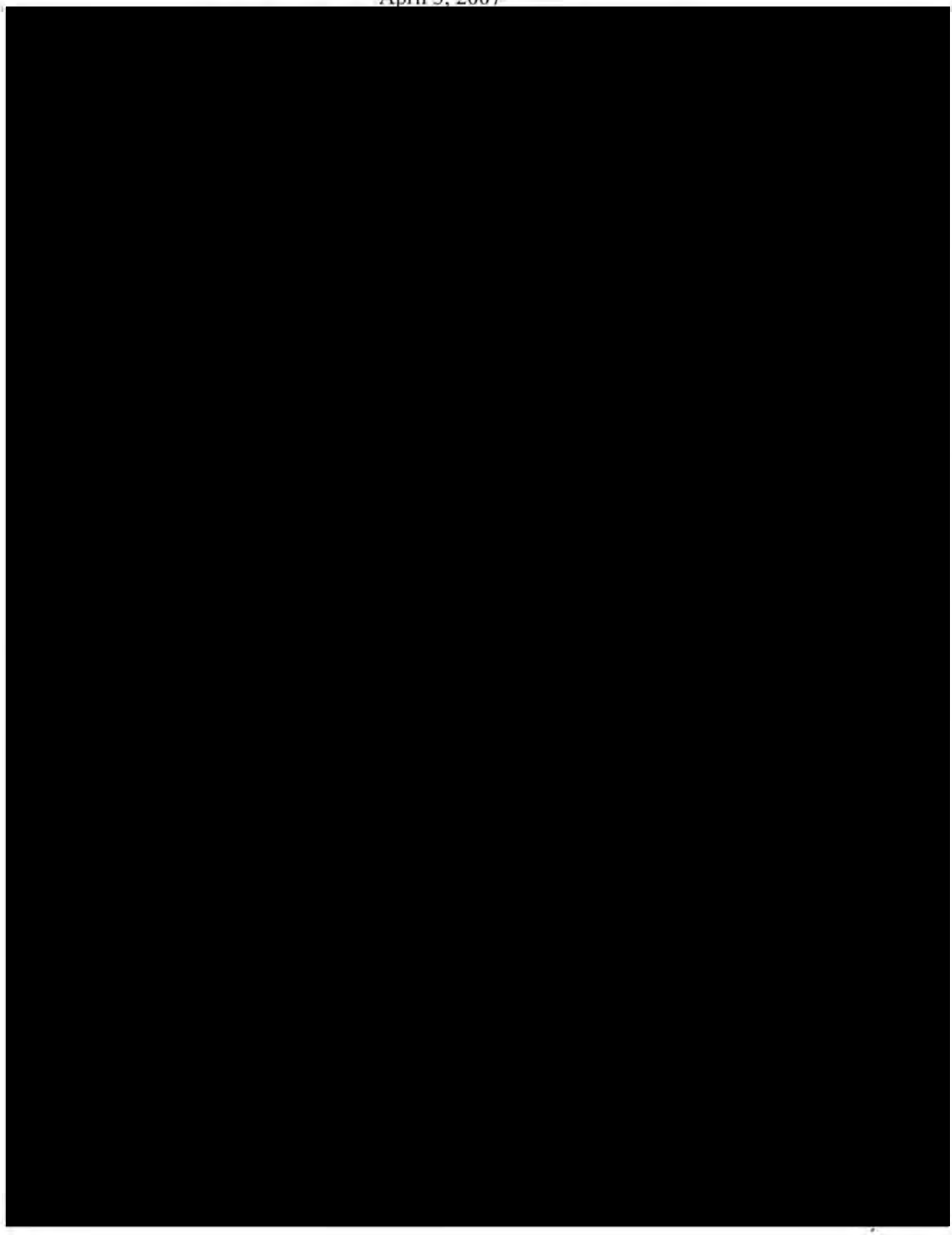
Attachment to Confidential Statements of Formula
EPA Form Number 8570-4
EPA Registration No. 71654-6; Virkon® S
EPA Registration No. 71654-7; Virkon®
April 3, 2007



Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Attachment to Confidential Statements of Formula
EPA Form Number 8570-4
EPA Registration No. 71654-6; Virkon® S
EPA Registration No. 71654-7; Virkon®
April 3, 2007



Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

Virkon® and Virkon® S
Alternate Formula Amendments April 3, 2007

Worksheet – Amount of Each Component in Formulation and Total (Block 17)

[redacted]

CONFIDENTIAL SUPPLEMENT TO EPA
APPLICATION FOR ALTERNATE FORMULATIONS

EPA REGISTRATION NUMBERS
71654-6
71654-7

V Beech

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 71654-6

Send to SIG: check box ☐

This material is:

- ☐ New stamped-accepted label
- ☐ New CSF
- ☐ Notification
- ☐ Final Printed Label
- ☒ Other: Add to file

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Stacey Grigsby

Phone: 305-6440 Division: AD

Date: 5/29/07

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A

PRODUCT REVIEWER: Stacey Grigsby		**RMB** II **TEAM** 34
Description of Action: change to 302		**EPA File Symbol/Reg No.** 71654-6
Decision No. 379500	**Submission No.** 807977	**Fee for Service Action Code:**
FQPA Action Code: 332	**Non-FQPA Action Code:**	**PRIA FEE AMOUNT:**

	DAY	MONTH	YEAR
APPLICATION DATE	23	March	2007
EPA PIN DATE	23	March	2007
DATE PM RECEIVED FROM FRONT END	02	April	2007
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			
DATE RECEIVED FROM SCIENCE			2007
DATE DUE TO PM			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

COMMENTS: Call Registrant and ask what is a "SACHET."

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B	For Arctic Slope Contract Only	
	Contract No.: 0052	*ARCTIC SLOPE*/MANAGER
	Final Task: Signature _____	_____ (Total hrs)
C	Reviewer Comments:	

DATE FEE PAID:	**RESPONSE CODE:** 1140 **RESPONSE DATE:** 5/29/07

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 29, 2007

Thomas C. McEntee
Product Registration Manager
E.I. Dupont De Nemours and Company
Post Office Box 80023
Wilmington, DE 19880-0402

Subject: **Virkon® S**
EPA Registration No.: 71654-6
Application Date: March 23, 2007
Receipt Date: March 28, 2007

Dear Mr. McEntee:

The following amendment, submitted as a notification was changed by the Agency to a label amendment. The amendment, submitted in connection with registration under section the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the reasons listed below:

Proposed Amendment:

- Add chart of Sachet Dilution Chart
- Delete M. bovis from page 3 and page 10 lines 3.

General Comment:

The addition of the claim "Sachet" will require air monitoring data to determine the air concentration in the premises. The Agency has no objections to you deleting the organism "*Mycobacterium bovis* (M.bovis)" from the label.

No air monitoring data was submitted to determine the air concentrations in the home.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Stacey Grigsby at (703) 305-6440.

Sincerely,

Stacey Grigsby

/s/ Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

March 23, 2007

Document Processing Desk
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Mr. Adam Heyward (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Notification: Deletion of the pest, *Mycobacterium bovis*

Dear Mr. Heyward,

Please consider the following in support of NOTIFICATION for the subject registration.

1. Application Form 8570-1 — 1 page
2. Revised Labeling (5 copies) deleting ***Mycobacterium bovis*** — 13 pages
   - •M. bovis Deleted - Page 3
   - •M. bovis Deleted - Page 10 Line 3
   - •Addition of Sachet Dilution Chart – Page 8 Lines 1-6

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

Virkon® S
Disinfectant and Virucide

BROAD SPECTRUM DISINIFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] {OPT}

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against
•Viruses
Including Canine Parvovirus [OPT}
•Bacteria
•Fungi

ACTIVE INGREDIENTS:	
Potassium peroxymonosulfate.....	21.41%
Sodium Chloride.....	1.50%
OTHER INGREDIENTS.....	77.09%
TOTAL.....	100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO
See Inside Booklet for Additional Precautions

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6 EPA Est. No. XXXXX-YY-ZZZ

Front Panel Continued

FIRST AID	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice.
If on Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice.
If Swallowed:	• Call Poison Control Center or doctor immediately for treatment advice. • Have Person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
HOT LINE NUMBER	
For 24-hour emergency information on this product, call 1-800-3637 (US & Canada) or 1-302-774-1100 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

ANIMAL AND ZOONOTIC PATHOGENS

BACTERIA

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

Not approved in California for use against the following bacteria:
Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:
Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exantherma Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

Not approved in California cont.

Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi- Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujesky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagropphytes (2%)

Not approved in California for use against the following fungi:
Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

PLANT PATHOGENS
Not approved in California for use against plant pathogens:
Alernaria solani
Botrytis cinera
Colletotrichum coccodes
Didymella bryoniae
Fusarium oxysporum
Fusarium solani
Penicillium oxalicum
Phomopsis sclerotioides
Pyrenochaeta lycoopersici
Pythium aphanidermatium
Rhizoctonia solani
Sclerotinia sclerotiorum
Thielaviopsis basicola
Verticillium dahliae
Xanthomonas axonopodis

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.
Corrosive statement refers to powder only not in use solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.

2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT]

Powder

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Quart	*0.15 ounces**	*0.3 ounces*	*0.7 ounces*
1 Gallon	*0.65 ounces**	*1.3 ounces*	*2.7 ounces*
10 Gallons	*6.7 ounces**	*13.4 ounces*	*26.7 ounces*
50 Gallons	*33.4 ounces**	*66.8 ounces*	*133.5 ounces*

Measuring cup provided.

Tablet

Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 Pint		*1 tablet*	*2 tablets*
1 Quart	*1 tablet**	*2 tablets*	*4 tablets*
1 Gallon	*4 tablets**	*8 tablets*	*16 tablets*

* The 0.5% solution currently is not approved for use in California.

Sachet Quantity of Water	*0.5% Solution**	*1% Solution*	*2% Solution*
1 gallon	-	*1 Sachet*	*2 Sachets*
2 Gallons	*1 Sachet*	*2 Sachets*	*4 Sachets*

* The 0.5% solution is currently not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of Streptococcus pyogenes, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella chloeraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Mycoplasma gallisepticum. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts) Aspergillus flavus, Fungi of Aspergillus fumigatus and Bacteria of Bordetella avium, Helicobacter pylori .

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

CONTROLS: Bacteria of Actinobacillus Pleuropneumoniae and Clostridium perfringens;. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of Fusarium moniliforme.Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exantherma, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.
Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.
Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4; *Not approved in California for use against the following organisms:* Bacteria of Moraxella bovis and Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. *Not approved in California for use against the following organisms:* Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems]within [associated with]Veterinary Medical Hospitals, infections disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.

4) Heavy growth of algae or fungi may have to be scrubbed off following application.

5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California:*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

Disease Organism	Dilution rate	Oz./Gal.
PCV2 Virus (PMWS)	1:200	0.7

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

the frequency of HVAC system treatments is to *"treat as required"*. The frequency of residential (and/or commercial/intuitional) HVAC treatments is expected to be minimal (one treatment per year may be an overestimate). In addition, the half-life of chlorine dioxide is rapid. Therefore, inhalation exposure is expected to be limited to short-term durations. The maximum value monitored by BCI (2002) during application and/or reentry was 0.02 ppm, below the RfC value of 0.05 ppm. Therefore, there are no inhalation risks of concern.

4.2.2.3 Continuous Release (Gas) Deodorizer

Product Use in Homes:

One product has been identified that is registered as a continuous release of chlorine dioxide gas in homes (EPA Reg. No. 70060-12). The product is packaged as a pouch or sachet. The product states that it *"...controls odor-causing bacteria, mold and mildew and chemical odors in confined spaces..."* and is for use in households, hospitals, and institutions. The product is packaged in 5, 10, 20, 50, 100, and 200 gram pouches/sachets. Household uses include refrigerators, shoes, closets, laundry hampers, cupboards, cabinets, drawers, diaper pails, pet areas, and basements. Other use sites of this product outside the home include gym lockers, automobiles, boat cabins, and trash cans.

No monitoring data are available to determine the air concentrations in the home. Therefore, a bounding estimate of air concentration is presented based on the application rate and the label-referenced longevity of the pouches/sachets. According to the label, the basement rate is 200 grams of product per 500 ft^2 of basement area for up to 2 months of treatment. A 500 ft^2 basement area is assumed to be equivalent to a volume of 4,000 ft^3 or 113 m^3 (i.e., 500 ft^2 x 8 ft ceiling). A linear release of the chlorine dioxide gas is assumed. Based on the rapid half-life of chlorine dioxide (~30 minutes for aqueous solution and reportedly shorter in air), it is assumed that a gas build up will not occur. The theoretical constant air concentration would be 0.52 ppm assuming no air exchange and no build up of chlorine dioxide over time because of the short half-life (i.e., label rate of 200 grams of 5% ai product/500ft^2 for 2 months, assuming an 8 ft ceiling). The RfC for long-term continuous exposure is 0.00007 ppm. Therefore, the theoretical concentration from the product's release is of concern. This bounding estimate of exposure can be refined by determining residential ventilation rates, identifying sensitive analytical detection methods (current sampling techniques do not have the capability of monitoring to a level of 0.00007 ppm), collecting monitoring data, and determining the number of hours an individual is exposed in treatment areas. However, before any refinements to these air concentration estimates are attempted, it should be determined if the product's efficacy can be maintained at the RfC of ~0.00007 ppm.

Product Use in Automobiles:

There are data available to assess the use of the continuous release deodorizer product in automobiles (e.g., EPA Reg. No. 70060-12). Two studies were submitted that measured chlorine dioxide air concentrations in automobiles (Wood and Gallo 1997, and Speronello 1998).

Wood and Gallo (1997) measured chlorine dioxide in a total of 16 automobiles (8 cars

parked outside and 8 cars parked inside a garage). Cars were parked in inside and outside parking lots to account for sunlight degradation of chlorine dioxide. The study author indicated that "*...approximately half the chlorine dioxide released was consumed by sunlight*". Cars parked outside were treated with 5, 15, 25, and 50 gram sachets while cars parked inside were treated with 5 and 25 gram sachets. An Interscan Digital Chlorine Dioxide Analyzer was used to measure chlorine dioxide inside the cars (LOD appears to be 0.01 ppm). To sample chlorine dioxide in the cars, tubes were inserted through the weather stripping of the doors to preclude dilution by opening the doors. Each car was sampled from 1 to 4 days. Samples were taken for some cars at 2, 4, 8, and 24 hours after placement of sachets and other cars at 24, 27, 29, 33, and 50 hours after placement of sachets and finally, some at 1, 2, 4, 8, 48, and 96 hours after placement of sachets. Duplicate and triplicate readings were recorded at each sampling interval at various locations in the cars (i.e., floor, bench, or face for a total of 2 or 3 samples per interval). It appears that reported air concentrations represent instantaneous measurements.

The maximum reported single reading for outdoor cars was 0.19 ppm for the 50 gram sachet and also 0.19 ppm for the indoor car with a 25 gram sachet. The maximum and average readings for all sampling intervals are reported in Table 4.6. Although some of the maximum single reading values of chlorine dioxide exceed the short-term residential inhalation toxicity of concern (i.e., level of concern is a RfC of 0.05 ppm), these maximum single readings are not meaningful to determine risk concerns when compared to the short-term inhalation RfC selected in this document. It is more appropriate to compare the peak measurements to the ACGIH STEL which is based on a 15-minute average. The highest maximum single reading of 0.19 ppm from this study does not exceed the STEL of 0.3 ppm. The average of all of the instantaneous readings is below the RfC and the STEL. In conclusion, the data presented by Wood and Gallo (1997) indicate that the concentration of chlorine dioxide remains below the STEL and the average of the single measurements does not exceed the RfC of 0.05 ppm. However, a more appropriate measurement would have been to sample over a period of time that is representative of the duration people spend in cars to obtain a time weighted average (TWA).

Table 4.6. Maximum and Average Chlorine Dioxide Measurements in Automobiles.

Chlorine Dioxide Reading (ppm)	Weight of Chlorine Dioxide Sachets			
	5 grams	15 grams	25 grams	50 grams
Cars Parked Outdoors				
Maximum single reading	0.01	0.06	0.1	0.19
Average of all readings	0.0005	0.009	0.011	0.029
Cars Parked Indoors				
Maximum single reading	0.008	Not Sampled	0.19	Not Sampled
Average of all readings	0.002		0.008	

LOD = 0.01 ppm.
"Average of all readings" represents the average where nondetects are counted as zero.

Speronello (1998) provided limited additional information on chlorine dioxide measurements inside of automobiles. Two cars using different application rates were monitored in this study (problems were encountered with the 3rd car and this experiment was discontinued). One car was treated with a 20 gram sachet and the other car was treated with three 20 gram sachets. Air concentrations in this study were measured with an INTERSCAN Digital Compact

the frequency of HVAC system treatments is to *"treat as required"*. The frequency of residential (and/or commercial/intuitional) HVAC treatments is expected to be minimal (one treatment per year may be an overestimate). In addition, the half-life of chlorine dioxide is rapid. Therefore, inhalation exposure is expected to be limited to short-term durations. The maximum value monitored by BCI (2002) during application and/or reentry was 0.02 ppm, below the RfC value of 0.05 ppm. Therefore, there are no inhalation risks of concern.

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parked outside and 8 cars parked inside a garage). Cars were parked in inside and outside parking lots to account for sunlight degradation of chlorine dioxide. The study author indicated that "*...approximately half the chlorine dioxide released was consumed by sunlight*". Cars parked outside were treated with 5, 15, 25, and 50 gram sachets while cars parked inside were treated with 5 and 25 gram sachets. An Interscan Digital Chlorine Dioxide Analyzer was used to measure chlorine dioxide inside the cars (LOD appears to be 0.01 ppm). To sample chlorine dioxide in the cars, tubes were inserted through the weather stripping of the doors to preclude dilution by opening the doors. Each car was sampled from 1 to 4 days. Samples were taken for some cars at 2, 4, 8, and 24 hours after placement of sachets and other cars at 24, 27, 29, 33, and 50 hours after placement of sachets and finally, some at 1, 2, 4, 8, 48, and 96 hours after placement of sachets. Duplicate and triplicate readings were recorded at each sampling interval at various locations in the cars (i.e., floor, bench, or face for a total of 2 or 3 samples per interval). It appears that reported air concentrations represent instantaneous measurements.

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Maximum single reading	0.008	Not Sampled	0.19	Not Sampled
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LOD = 0.01 ppm.
"Average of all readings" represents the average where nondetects are counted as zero.

Speronello (1998) provided limited additional information on chlorine dioxide measurements inside of automobiles. Two cars using different application rates were monitored in this study (problems were encountered with the 3rd car and this experiment was discontinued). One car was treated with a 20 gram sachet and the other car was treated with three 20 gram sachets. Air concentrations in this study were measured with an INTERSCAN Digital Compact

Portable Analyzer (model 4335DG). This device recorded chlorine dioxide measurements at 10 second intervals for 5 minutes. Sampling intervals were 0, 1, 2, 4, 6, 8, 24, 101, 149, and 192 hours after initial placement of the sachet. All of the 5 minute samples in the car treated with 20 grams of chlorine dioxide are below the detection limit of 0.05 ppm. The results from the car with the exaggerated application rate indicated a maximum chlorine dioxide concentration of 0.091 ppm. However, the text did not indicate if this was a 5 minute sample or peak 10 second interval within the 5 minute measurement. It also appears that some of the data tables in Speronello (1998) are missing from the experiment identified as "*Run 3*". The data table for "*Run 3*" only includes the 10 second measurements for the 0 hours after treatment interval. The results of this second study do not raise any additional concerns for peak measurements, however, the data are of limited use to determine a TWA concentration over the time period people spend in cars.

4.2.2.4 Swimming Pools & Spas

Sodium chlorite is used to treat circulation systems in swimming pools & spas (EPA Reg. No. 70060-20). The use directions for treating the circulation systems include the following types of statements:

- Do not add this product through any automatic dispensing device;
- Apply product when no persons are in the pool;
- For pools leave pump off for 6 to 12 hours before resuming pumping and then wait at least 8 hours before allowing swimmers to enter pool;
- Frequency of application is once every 3 – 4 weeks for pools and once every 4 – 6 weeks for spas; and
- For spas wait approximately 30 minutes before reusing spa.

Based on the intended use of the product, swimming in pools or spas treated with chlorine dioxide is not assessed quantitatively. When use directions are properly followed, dermal, incidental oral, and inhalation exposures to chlorine dioxide residual levels after the cleaning of the circulation systems are expected to be minimal.

4.2.3 Data Limitations/Uncertainties

There are several data limitations and uncertainties associated with the residential handler and post application exposure assessments. These include:

- The exposure factors used to calculate daily exposures to handlers are based on applicable data, if available. For lack of appropriate data, values from a scenario deemed similar enough by the assessor were used.
- Surrogate dermal unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (MRID 42587501) or from the Pesticide Handler Exposure Database (PHED, 1998). See Appendix A for summaries of these data sources.
- The amounts handled/treated were estimated based on information from various sources, including the Draft Standard Operating Procedures (SOPs) for Residential Exposure

6.1.2 Inhalation Handler Exposures

Inhalation exposure to the release of chlorine dioxide gas during the mixing/loading/application of products producing chlorine dioxide may occur. Because the inhalation toxicological endpoint is based on an 8-hour TWA, the assessment of handler inhalation exposures is assessed as a combination of activities throughout a work day. The assessment of inhalation exposure is presented in the post application/bystander section (Section 6.2).

As indicated above, EPA has selected an 8-hour TWA inhalation endpoint. EPA does not provide a separate endpoint for short-term exposures to handlers. Short-term releases of chlorine dioxide are of concern for accidental releases/leaks and/or when applicators are in close proximity to open solutions of chlorine dioxide. EPA assumes that the ACGIH 15 minute short term exposure limit (STEL) of 0.3 ppm as well as the immediately dangerous to life or health (IDLH) limit of 5 ppm will be adhered to in the industries using chlorine dioxide.

6.2 Occupational Post Application/Bystander Exposure

6.2.1 Dermal Post Application/Bystander Exposures

No information is available to assess post application/bystander dermal exposure to uses in agricultural premises as well as food handling, commercial/institutional and medical premises; human drinking water facilities; industrial processes; and retention ponds. However, dermal post application exposure to chlorine dioxide is expected to be less than that of the dermal contact of children playing on treated floor surfaces. Therefore, the dermal exposure route is not believed to be of concern in these industries.

6.2.2 Inhalation Post Application/Bystander Exposures

Non-Fogging Uses

There is the potential for the off gassing of chlorine dioxide during some applications that are not totally enclosed (e.g., spray aqueous solution, mopping, pouring, etc). Although no occupational air monitoring data have been submitted to assess the inhalation route, EPA has obtained air concentration measurements from OSHA. OSHA maintains a data base known as the Integrated Management Information System (IMIS). The IMIS entries for chlorine dioxide are available for 7 industry Standard Industrial Classification (SIC) codes. Specific uses such as applicators, bystanders and the activities involved are not available. The SIC codes representing the chlorine dioxide data in IMIS used in this assessment include:

- SIC 0723 Crop preparation services for market;
- SIC 1629 Heavy construction;
- SIC 2611 Pulp mills;
- SIC 2621 Paper mills;
- SIC 2819 Industrial inorganic chemicals;
- SIC 2836 Biological products; and

- SIC 3999 Manufacturing industries.

The data selected for this analysis include only those samples that are reported as 8-hour TWA measurements from personal air samplers. Other samples, such as peaks concentrations and/or area monitors, have been omitted. The chlorine dioxide sampling and analytical procedures used in the collection of the data in IMIS are available at http://www.osha.gov/dts/sltc/methods/inorganic/id202/id202.html. The quantitative LOD from this method is 0.004 ppm for a 4-hour sample (the recommended sampling time). The reported full 8-hour work shift samples are based on two 4-hour samples collected in sequence. The inhalation endpoint selected by EPA is 0.003 ppm, just below the OSHA LOD for an 8-hour TWA air sample [i.e., (0.5 x 0.004 ppm per 4 hrs) + (0.5 x 0.004 ppm per 4 hrs)=0.004 ppm per 8 hours].

The summary results of the 33 observations taken from 8-hour TWA personal air samplers for chlorine dioxide are provided below in Table 6.5. All values, including ½ LOD are above the EPA selected inhalation reference concentration (RfC) of 0.003 ppm, and therefore, are of concern. Of the 33 TWA measurements available, 21 of those measurements were below the LOD of 0.004 ppm. In addition, of the 33 TWA measurements, only 3 were at or above the OSHA PEL of 0.1 ppm. For nondetected samples, 1/2 the detection limit for an 8-hour sample was used to determine the summary.

Table 6.5. Chlorine Dioxide 8-hour TWA for Personal Air Samplers from OSHA's IMIS Data Base.

Statistic	Chlorine Dioxide 8-hr TWA (ppm)	MOE
Arithmetic mean ± std	0.034 ± 0.096	The inhalation endpoint is expressed as the RfC. Because the uncertainty factors are included in the RfC a separate MOE is not needed. The occupational RfC of 0.003 ppm is compared directly to the air concentration monitored for the worker. Air concentrations above the RfC are of concern. All values, including the LOD, are above the RfC.
50^{th}%tile	0.004 (1/2 8-hr LOD)	
75^{th}%tile	0.008	
90^{th}%tile	0.032	
Maximum	0.42	
Number of Observations	33	
Number of Nondetects	21	

Fogging Uses

The fogging use of chlorine dioxide is unique such that no persons are present during the actual application/fogging. There is also a greater potential for chlorine dioxide gas formation from fogging then an aqueous-based application such as mopping. Therefore, a separate assessment is presented for foggers that indicate potential inhalation exposure and reentry recommendations. The air concentration in a fogged area should be below the occupational RfC of 0.003 ppm before the room is entered by persons not wearing respiratory protection. In the fogging assessment below, EPA Reg. No. 74602-2 is used to illustrate potential air concentrations.

Concentrations of chlorine dioxide were estimated for buildings after fogging applications. Air concentrations were calculated using the Multi-Chamber Concentration and Exposure Model (MCCEM v1.2). MCCEM estimates average and peak indoor air concentrations of chemicals released from products or materials in houses, apartments, townhouses, or other residences. Although the data libraries contained in MCCEM are limited to residential settings, the model can be used to assess other indoor environments. MCCEM has the capability to estimate inhalation exposures to chemicals, calculated as single day doses, chronic average daily doses, or lifetime average daily doses.

The product, EPA Reg # 74602-2 (sodium chlorite with a 5% chlorine dioxide equivalent) has a maximum application rate for egg houses of 0.0083 lb ai/gal (1000 ppm chlorine dioxide treatment solution). This particular product specifically lists a Dramm fogger for the application (i.e., ultra low volume (ULV)). According to the registrant, the Dramm fogger for chlorine dioxide applications uses 2.5 ounces of the diluted product per 225,000 cubic feet (USEPA 2006), and the label states to run the fogger for five minutes. **Note: This labeled rate should be added to all chlorine dioxide fogger uses. If other registrants require a higher application rate, these rates need to be brought to EPA's attention during the development of the chlorine dioxide RED.**

Model input assumptions for MCCEM and the calculated exposures are presented in Tables 6.6 and 6.7 for 0.18 ACH and 4 ACH, respectively. The following assumptions were made:

- The area being fogged is a one-chamber barn with dimensions of 300 ft x 50 ft x10 ft (AD standard assumption).
- Two different air exchange rates (k_{ACH}) were used in the calculations: 0.18 air exchange per hour (ACH) (MCCEM default based on a poorly vented residential home) and 4 ACH based on the rate for a poultry barn (Jacobson, 2005).
- The half-life of chlorine dioxide is 30 minutes (0.5 hours) in an aqueous solution (believed to be less in air but reliable data are not available). Using the equation $\frac{1}{2}C_0 = C_0 e^{-k_{decay}t}$, and substituting 0.5 hours for "t", the rate of decay is calculated to be 1.386/hr.
- Both air exchange and chemical decay can be modeled as first-order processes for a well-mixed single chamber (i.e., the rate of chemical loss that can be attributed to either of these processes is proportional to the quantity of chemical in the chamber). Therefore, the two rates (k_{ACH} and k_{decay}) can be added together to form a single loss rate ($k_{loss}=k_{ACH}+k_{decay}$), such that $C(t) = C_0 e^{-k_{loss}t}$. This value was used for the "Air Exchange Rate" in the MCCEM model to account not only for the air exchange, but also the decay.
- Fogging occurs instantaneously, so that the entire mass of product is mixed homogeneously with the indoor air as soon as fogging commences.

The initial concentrations of chlorine dioxide, as indicated in Tables 6.6 and 6.7, is 0.0116 mg/m^3 or 0.004 ppm. Using an ACH of 0.18, an 8-hr TWA of less than 0.003 ppm (0.0084 mg/m^3) is expected with no REI. Using an ACH of 4/hr, an 8-hr TWA of less than 0.003 ppm (0.0084 mg/m^3) is expected without an REI. A detailed report is presented in Appendix C, including hourly air concentrations. Although there appears to be no inhalation risks of concern,

a 1-hour REI would be prudent. Moreover, potential label language to assure proper ventilation if rates above that used in this assessment are identified for existing products include:

--ten air exchanges, or
--2 hours of mechanical ventilation (i.e., fans), or
--4 hours of passive ventilation (i.e., windows, vents), or
--11 hours of no ventilation followed by 1 hour of mechanical ventilation, or
--11 hours of no ventilation followed by 2 hours of passive ventilation, or
--24 hours of no ventilation

Table 6.6. Short and Intermediate Term Inhalation Risks Associated with Post Application Exposure to Chlorine Dioxide After Fogging 0.18 ACH

Parameter[a]	Value		Rationale
Dimensions	300x50x10 ft, 15,000 ft^2 floor area, 150,000 ft^3 (4,248 m^3) volume		EPA assumption
Air Changes per Hour (ACH)*	1.566/hr		Value used in MCCEM is actually the ACH rate (0.18/hr) plus the decay rate (1.386/hr)[a]
Activity Pattern*	8-hour Time Weighted Average (TWA) starting immediately, 1 hour, and 12 hours after fogging		Based on product=s re-entry interval (EPA Reg# 74602-2)
Application Rate	0.0083 lb ai/gal		Product label
Use Rate	2.5 oz/225,000 ft^3		Manufacturer's specifications
Amount Applied to Room	$1.16x10^{-5}$ g/m^3		(Use rate) x (Application rate)
Concentration in Room after Fogging (initial concentration rate at time 0)*	0.0116 mg/m^3		Amount applied to room
MCCEM Output			
Average Concentration over 8-hrs (mg/m^3)	0-hr re-entry:	0.00109	Average of MCCEM-calculated air concentrations from Hour 0 to Hour 8
Average Concentration over 8-hrs (mg/m^3)	1-hr re-entry:	0.000227	Average of MCCEM-calculated air concentrations from Hour 1 to Hour 9
Occupational RfC (i.e., level-of-concern)	8-hour TWA	0.0084(mg/m^3)	Level-of-concern not exceeded

*Used as MCCEM input. Default values from MCCEM were used for all inputs not listed in the table above

[a] Half-life of chlorine dioxide = 30 minutes (0.5 hr). Using the equation $\frac{1}{2}C_0 = C_0 e^{-k_{decay} t}$ and substituting 0.5 hours for "t", the rate of decay is calculated to be 1.386/hr.

Table 6.7. Short and Intermediate Term Inhalation Risks Associated with Post application Exposure to Chlorine Dioxide After Fogging 4 ACH			
Parameter[a]	Value		Rationale
Dimensions	300x50x10 ft, 15,000 ft^2 floor area, 150,000 ft^3 (4,248 m^3) volume		EPA assumption
Air Changes per Hour (ACH)*	5.386/hr		Value used in MCCEM is actually the ACH rate (4.0/hr) plus the decay rate (1.386/hr)[a]
Activity Pattern*	8 hour Time Weight Average (TWA) starting immediately, 30 minutes, and 1 hour after fogging		Based on product=s re-entry interval (EPA Reg# 74602-2)
Application Rate	0.0083 lb ai/gal		Product label
Use Rate	2.5 oz/225,000 ft^3		Manufacturer's specifications
Amount Applied to Room	$1.16x10^{-5}$ g/m^3		(Use rate) x (Application rate)
Concentration in Room after Fogging (initial concentration rate at time 0)*	0.0116 mg/m^3		Amount applied to room
MCCEM Output			
Average Concentration over 8-hrs (mg/m^3)	0-hr re-entry:	0.000475	Average of MCCEM-calculated air concentrations from Hour 0 to Hour 8
Average Concentration over 8-hrs (mg/m^3)	1-hr re-entry:	$2.18x10^{-6}$	Average of MCCEM-calculated air concentrations from Hour 1 to Hour 9
Occupational RfC (i.e., level-of-concern)	8-hour TWA	0.0084(mg/m^3)	Level-of-concern not exceeded

*Used as MCCEM input. Default values from MCCEM were used for all inputs not listed in the table above

[a] Half-life of chlorine dioxide = 30 minutes (0.5 hr). Using the equation $\frac{1}{2}C_0 = C_0 e^{-k_{decay} t}$ and substituting 0.5 hours for "t", the rate of decay is calculated to be 1.386/hr.

In a second fogging example, EPA Reg. No. 21164-3 allows chlorine dioxide fogging and misting applications while workers are in the room if the level of chlorine dioxide does not exceed the TLV-TWA of 0.1 ppm. The use directions are as follows:

> *"...may be added to the plant misting or fogging systems to deodorize and to control odor causing bacteria, mold and mildew in food processing plants, dairies, bottling plants, poultry, meat and fish plants and animal facilities such as poultry houses, swine pens, calf barns and kennels. If the TLV-TWA is to be exceeded, turn off air handlers and*

vacate people and livestock from the rooms to be fogged or misted. Ventilate for 15 minutes prior to reentry. Note – Be careful not to add concentrated acid solutions to undiluted DURA KLOR as high concentrations of chlorine dioxide gas may evolve. The concentration of chlorine dioxide in the diluted DURA KLOR solution should not be allowed to exceed 0.5 ppm..."

The occupational RfC of 0.003 ppm could be exceeded based on these use directions (i.e., workers do not need to leave treatment area unless the TLV-TWA of 0.1 ppm is exceeded).

EPA's Risk-based RfC versus OSHA PEL

It is also important to note that the OSHA PEL for chlorine dioxide is 0.1 ppm. Air concentrations above the PEL are assumed to be mitigated at each facility. Facilities using chlorine dioxide are not required to mitigate inhalation exposures until the air concentration reaches 0.1 ppm. Based on the occupational inhalation toxicological endpoint selected for chlorine dioxide (i.e., RfC of 0.003 ppm), levels at or near the PEL are of concern. In fact, the capability (i.e., LOD) of the OSHA sampling method is insufficient for the occupational RfC presented in this document. Reconciliation of the EPA risk-based RfC and the current OSHA standards will be made during the regulatory decision phase of the Reregistration Eligibility Decision (RED) for chlorine dioxide. The various cited chlorine dioxide levels from other organizations are reported in Table 6.8 for review by regulatory managers.

Table 6.8 Chlorine Dioxide Regulatory Levels.

Organization	Time/Duration	Description	Air Concentration (ppm)
OSHA	8-hour TWA	PEL	0.1
ACGIH	8-hour TWA	TLV	0.1
	15-minutes	STEL	0.3
NIOSH	10-hour TWA	REL	0.1
	30-minutes (escape)	IDLH	5
EPA	8-hour TWA	RfC - Occupational	0.003
	"Short-term"	RfC – Residential for single exposures	0.05
	Continuous (24/7)	RfC – Residential	0.00007

6.3 Data Limitations/Uncertainties

There are several data limitations and uncertainties associated with the occupational handler and post application exposure assessments. These include:

$ The exposure factors used to calculate daily exposures to handlers are based on applicable data, if available. For lack of appropriate data, values from a scenario deemed similar enough by the assessor were used.
$ The inhalation toxicological endpoints of concern for the occupational and long-term residential scenarios/durations are below the limit of detection for chlorine dioxide.
$ Specific application techniques and/or worker activities are not available in OSHA's IMIS data base.

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA	United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [ ] Amendment [X] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71654-6	Adam Heyward	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Virkon (R) S	34	

5. Name and Address of Applicant *(Include ZIP Code)*

E.I. du Pont de Nemours and Company
Attn: Thomas C. McEntee
Dupont Chemical Solutions Enterprise, P. O. Box 80402
Wilmington, DE 19880-0402

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[X] Notification - Explain below.

[ ] Final printed labels in repsonse to Agency letter dated _____

[ ] "Me Too" Application.

[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of deletion of the pest, Mycobacterium bovis, per PR Notice 98010 II.B. Optional Water-Soluble packaging per PR Notice 98-10 II.E.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation sat 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I nuderstand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I furhter understnad that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be inviolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[X] Yes [ ] No	[X] Yes [ ] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt: 1.3 oz. / No. per container: 50	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	10 lb., 4 lb, 1lb., 9 oz.,	[X]

6. Manner in Which Label is Affixed to Product [x] Lithograph Paper glued Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas C. McEntee	Product Registration Manager	302 695 6856

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
[signature]	Product Registration Manager	
4. Typed Name	**5. Date**	
Thomas C. McEntee	March 23, 2007	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

May 18, 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Certified Mail

Thomas C. McEntee
Dupont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, Delaware 19880-0402

Subject: **Regarding 6(a)(2):** Failure of Performance Information for the Product Virkon® S
EPA Registration Number: 71654-6
MRID Number: 47071801; Final Report, "H-27069, H-27070and H-27071: Tuberculocidal Activity of Disinfectants"
PC Code: 063604 – Potassium Peroxymonosulfate

Attention:

We have completed the screen and review of the efficacy data submitted under section 6 (a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) addressing the efficacy failures for the product DuPont™ RelyOn™ Multi-Purpose Disinfectant Cleaner (EPA Reg. No. 71654-7) also known as "Virkon®".

Virkon® S and Virkon® (EPA Reg. Nos. 71654-6 and 71654-7, respectively), are registered disinfectants, virucides and fungicides. Virkon® S is also registered tuberculocide. The 6(a)(2) package was submitted to demonstrate efficacy of Virkon® (EPA Reg. No. 71654-7) against *Mycobacterium bovis* in the presence of 5% organic soil for a contact time of 10 minutes, in a 3% solution prepared in 400ppm AOAC Hard Water.

The Agency standards for tuberculocidal claims are defined in DIS/TSS-6. Briefly, effectiveness against *M. tuberculosis* must be substantiated with data derived on 10 carriers by the AOAC Tuberculocidal Activity Method (II. Confirmative *In Vitro* Test for Determining Tuberculocidal Activity), for each of 2 samples representing 2 different batches of a liquid product under test. If the product is a spray, the procedure must be modified to conform with the AOAC Germicidal Spray Products Test using the media, microorganisms, and other elements described in the AOAC Tuberculocidal Activity Method. Killing of the test microorganism on all carriers, and no growth in any of the inoculated tubes of two additional media. The efficacy testing for the effectiveness of this product against *M. Bovis* was MicroBio Test, Inc. The testing was conducted according to Agency standards using Good Laboratory Practices. Under the conditions of this study, Virkon® was **not** effective as a tuberculocidal against *Mycobacterium bovis*.

The results are as follows:

Lot No. 24288
Results Expressed as Number of Tubes Exhibiting Growth/total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	7/10	10/10

Lot No. 24290
Results Expressed as Number of Tubes Exhibiting Growth/total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	7/10	6/10

Lot No. 26534
Results Expressed as Number of Tubes Exhibiting Growth/total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	6/10	8/10

The data revealed lack of efficacy of Virkon® (EPA Reg. No. 71654-7) against *Mycobacterium bovis*. The product in question is the same composition of Virkon® S (EPA Reg. No. 71654-6), which supports a tuberculocidal claim. Since the compositions are identical, the Agency is requesting removal of the tuberculocidal claim from the last accepted label for Virkon® S, stamped July 26, 2006.

Please respond within 30 days from the date of this letter stating your intentions to comply with the information and/or data requests cited above. If we do not hear from you within (30) days, with your intention to comply, we will have to submit this information to OECA for further enforcement actions.

When submitting information and/or data, please reference the date of this correspondence in your response and use one of the following addresses listed below:

For delivery by mail:

Document Processing Desk - 6(a)(2)
Office of Pesticide Programs – 7504P
US EPA
Attn: Wanda Hall
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460-2001

For delivery by courier:

Document Processing Desk - 6(a)(2)
Office of Pesticide Programs
Attn: Wanda Hall
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, Virginia 22202

If you have any questions regarding this letter, you may contact me at (703) 308-6383 or via email Hall.Wanda@epa.gov.

Sincerely,

Wanda Hall

Wanda Hall
Program Analyst
Office of Pesticide Programs
Antimicrobials Division/Immediate Office (7510P)

cc: Kathleen O'Malley, IRSD
Juanita Cherry, AD/IO
Kennetta Calloway, AD/IO
Michele Wingfield, AD/PSB
Tajah Blackburn, AD/PSB
Frank Sanders, AD/Division Director
Betty Shackleford, AD/Associate Director

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

May 17, 2007

MEMORANDUM

Subject: 6(a)2 Review for EPA Reg. No. 71654-6, Virkon S; DP Barcode: 339194

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Wanda Hall
Risk Manager Review
Antimicrobials Division (7510P)

Action: Expedited Review

I BACKGROUND

Virkon S and Virkon (EPA Reg. Nos. 71654-6 and 71654-7, respectively), are registered disinfectants, virucides, and fungicides. Virkon S is also registered tuberculocide. The 6(a) (2) package was submitted to demonstrate efficacy of Virkon (EPA Reg. No 71654-7) against *Mycobacterium bovis* in the presence of 5% organic soil for a contact time of 10 minutes, in a 3% solution prepared in 400 ppm AOAC Hard Water.

II AGENCY STANDARDS FOR CLAIM

The Agency standards for tuberculocidal claims are defined in DIS/TSS-6. Briefly, effectiveness against *M. tuberculosis* must be substantiated with data derived on 10 carriers by the AOAC Tuberculocidal Activity Method (II. Confirmative *In Vitro* Test for Determining Tuberculocidal Activity) for each of 2 samples representing 2 different batches of a Liquid product under test. If the product is a spray, the procedure must be modified to conform with the AOAC Germicidal Spray Products Test using the media, microorganisms, and other elements described in the AOAC Tuberculocidal Activity Method. Killing of the test microorganism on all carriers, and no growth in any of the inoculated tubes of two additional media. The efficacy testing for the effectiveness of this product against *M. bovis* was MicroBioTest, Inc. The testing was conducted according to Agency standards using Good Laboratory Practices.

III SYNOPISIS OF STUDY

1. MRID No. 470718-01, "H-27069, H-27070, and H-27071: Tuberculocidal Activity of Disinfectants" by Jennifer L. Tester. Study conducted at MicroBioTest, Inc. Study completion date—February 21, 2007. Laboratory Project Identification Number—473-119.

This study was conducted against *Mycobacterium bovis* (BCG) (Organon Teknika, Corp). Three lots (Lot Nos. 24288, 24290, 26594) of the product, DuPont RelyOn Multi-Purpose Disinfectant Cleaner, were tested using the in vitro test for tuberculocidal activity published in the Official Methods of Analysis, 16th edition, AOAC (1995), and the EPA Guidelines DIS/TSS-2 & 6. A 3% test solution was prepared by diluting 3 grams of the test agent in 97 g of diluent (400 ppm AOAC hard water). Heat-inactivated fetal bovine serum was added to the inoculum to represent 5% organic soil load. Carriers were placed in 15-20 ml of *M. bovis* for 15 minutes. Carriers were removed, and dried for 30 minutes at 37±2°C. Inoculated carriers were added to 10 ml of the test substance for a contact time of 10 minutes. Following exposure, carriers were neutralized for at least 10 minutes. Neutralized carriers were transferred to 20 ml of MPBM. From each tuber of neutralizer, 2 ml were subcultured to a tube containing 20 ml of 7H9 and 2 ml were subcultured to a tube containing 20 ml of Kirchner's medium. All primary and secondary subcultures were incubated for 60 days at 37±2°C, and the results were recorded. If no subculture showed visible growth at the conclusion of the 60-day incubation period, the period was extended an additional 30 days. Controls included those for viability, neutralizer effectiveness, sterility, carrier count, and challenge microorganism confirmation.

Note: DuPont RelyOn Multi-Purpose Disinfectant Cleaner (EPA Reg. No. 71654-7) is also known as Virkon.

IV RESULTS

Lot No. 24288
Results Expressed as Number of Tubes Exhibiting Growth/Total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	7/10	10/10

Lot. No. 24290
Results Expressed as Number of Tubes Exhibiting Growth/ Total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	7/10	6/10

Lot No. 26534
Results Expressed as Number of Tubes Exhibiting Growth/ total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	6/10	8/10

Control Carriers Counts 1.1×10^6 CFU/carrier

Comments: Data revealed lack of efficacy of Virkon (EPA Reg. No. 71654-7) against *Mycobacterium bovis*. The product in question is the same composition of Virkon S (EPA Reg. No. 71654-6), which supports a tuberculocidal claim. Since the compositions are identical; the Agency is requesting removal of the tuberculocidal claim from Virkon S (EPA Reg. No. 71654-6).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

April 26, 2007

MEMORANDUM

Subject: 6(a)2 Review for EPA Reg. No. 71654-6, Virkon S; DP Barcode: 339194

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P) 4/26/07

Thru: Michele Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Wanda Hall
Risk Manager Review
Antimicrobials Division (7510P)

Action: Expedited Review

Comments: Data revealed lack of efficacy of Virkon (EPA Reg. No. 71654-7) against *Mycobacterium bovis*. The product in question is the same composition of Virkon S (EPA Reg. No. 71654-6), which supports a tuberculocidal claim. Since the compositions are identical, the Agency is requesting removal of the tuberculocidal claim from Virkon S (EPA Reg. No. 71654-6).

I SYNOPISIS OF STUDY

1. MRID No. 470718-01, "H-27069, H-27070, and H-27071: Tuberculocidal Activity of Disinfectants" by Jennifer L. Tester. Study conducted at MicroBioTest, Inc. Study completion date—February 21, 2007. Laboratory Project Identification Number—473-119.

This study was conducted against *Mycobacterium bovis* (BCG) (Organon Teknika, Corp). Three lots (Lot Nos. 24288, 24290, 26594) of the product, DuPont RelyOn Multi-Purpose Disinfectant Cleaner, were tested using the in vitro test for tuberculocidal activity published in the Official Methods of Analysis, 16th edition, AOAC (1995), and the EPA Guidelines DIS/TSS-2 & 6. A 3% test solution was prepared by diluting 3 grams of the test agent in 97 g of diluent (400 ppm AOAC hard water). Heat-inactivated fetal bovine serum was added to the inoculum to represent 5% organic soil load. Carriers were placed in 15-20 ml of *M. bovis* for 15 minutes. Carriers were removed, and dried for 30 minutes at 37±2°C. Inoculated carriers were added to 10 ml of the test substance for a contact time of 10 minutes. Following exposure, carriers were neutralized for at least 10 minutes. Neutralized carriers were transferred to 20 ml of MPBM. From each tuber of neutralizer, 2 ml were subcultured to a tube containing 20 ml of 7H9 and 2 ml were subcultured to a tube containing 20 ml of Kirchner's medium. All primary and secondary subcultures were incubated for 60 days at 37±2°C, and the results were recorded. If no subculture showed visible growth at the conclusion of the 60-day incubation period, the period was extended an additional 30 days. Controls included those for viability, neutralizer effectiveness, sterility, carrier count, and challenge microorganism confirmation.

Note: DuPont RelyOn Multi-Purpose Disinfectant Cleaner (EPA Reg. No. 71654-7) is also known as Virkon.

II RESULTS

Lot No. 24288
Results Expressed as Number of Tubes Exhibiting Growth/Total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	7/10	10/10

Lot. No. 24290
Results Expressed as Number of Tubes Exhibiting Growth/ Total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	7/10	6/10

Lot No. 26534

Results Expressed as Number of Tubes Exhibiting Growth/ total Number of Tubes

Day	Media			
	MPBM+	MPBM	7H9	KM
60	0/10	1/10	6/10	8/10

Control Carriers Counts 1.1×10^6 CFU/carrier

AD 6(A)2 CHECKLIST

Date Received By Reviewer April 20, 2007

General Information	
Company Name:	**Dupont Chemical Solutions Enterprise**
Chemical Name:	**Potassium Peroxymonosulfate (Virkon ®S)**
Registration #:	**71654-7**
MRID(s):	**47071800**

Screening Codes – No Action		
Code	*Code Description*	*Check Selection*
PD	Pending	
N1	Wait for Full Study	
N2	Aggregate With Similar Information	
N3	No Products Registered	
N4	New Chemical	
N5	Supplemental Information	
N6	Report Sketchy	

Screening Codes – Review		
Code	*Code Description*	*Check Selection*
R2	Expedited Schedule	
R3	Non-expedited Schedule	
R4	Expedited Schedule – Label Change Likely	✓

Outcome Codes		
Code	*Code Description*	*Check Selection*
Code 1	No Further Action Necessary	
Code 2	Tolerance Revisions Initiated	
Code 3	Label Changes Initiated	✓
Code 4	Additional Data Required	
Code 5	Voluntary cancellation	
Code 6	Risk Review	
Code 7	Pending	
Code 8	Risk Mitigation	
Code 9	Superseded by Other Information	
Code 10	Reregistration / RED	
Code 11	Special Review	
Code 12	Enforcement – Stop Sale	
Code 13	Change in Regulatory Authority	
Code 14	Antimicrobial Testing Program	

AD Reviewer _____

Date Completed 4/26/07

DATA PACKAGE BEAN SHEET

Date: 17-May-2007

Decision #: 378316

DP #: (339194)

NON PRIA

Parent DP#:

* * * Registration Information * * *

Registration: 71654-6 - VIRKON S

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 34 - Adam Heyward - (703) 308-6422 Room# PY1 S-8238

Risk Manager Reviewer: Wanda Hall WHALL

Sent Date: 06-Mar-2007 Calculated Due Date: 14-May-2007 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (405) ADVERSE DATA (6A2);

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxymonosulfate(20.4%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 20-Apr-2007 Due Back:

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxymonosulfate

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	AD / PSB	20-Apr-2007		Last Possible Science Due Date: 19-Apr-2007
Team Name:	EET	20-Apr-2007		Science Due Date: 04-May-2007
Reviewer Name:	Blackburn, Tajah	20-Apr-2007	17-May-2007	Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please screen the attached 6(a)(2) data package and provide explanation whether or not it needs to be placed in expedited review.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 7, 2007

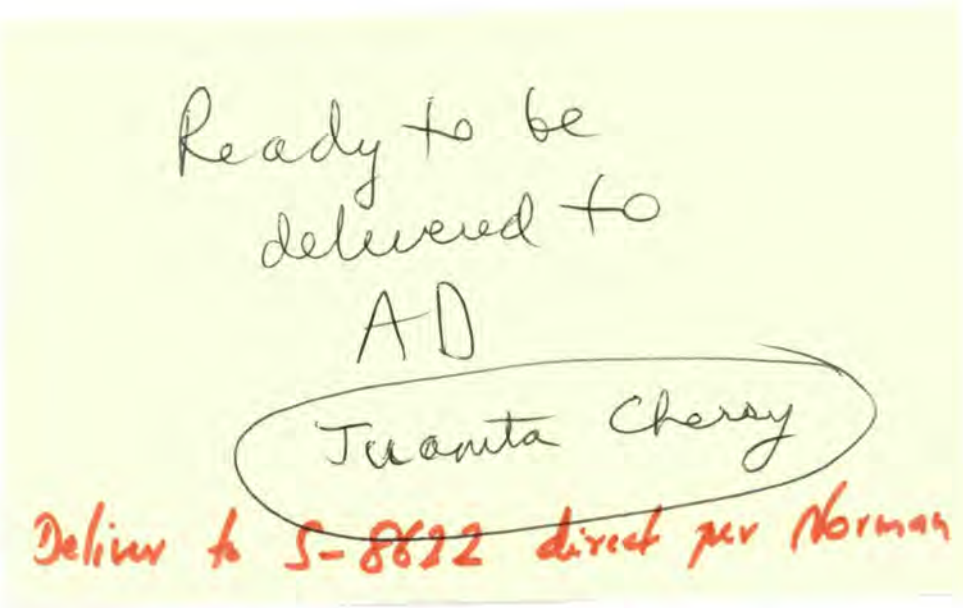
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

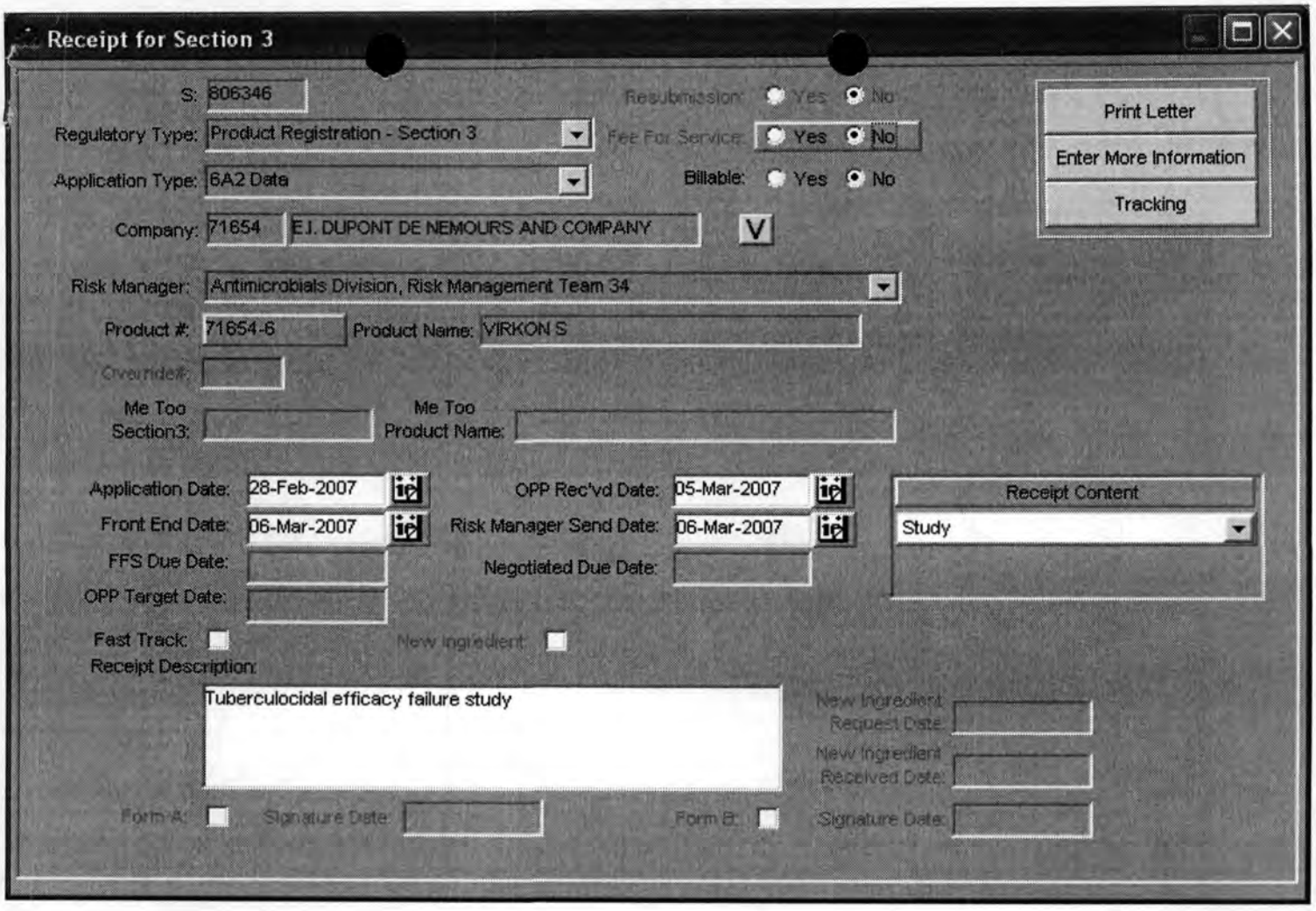
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

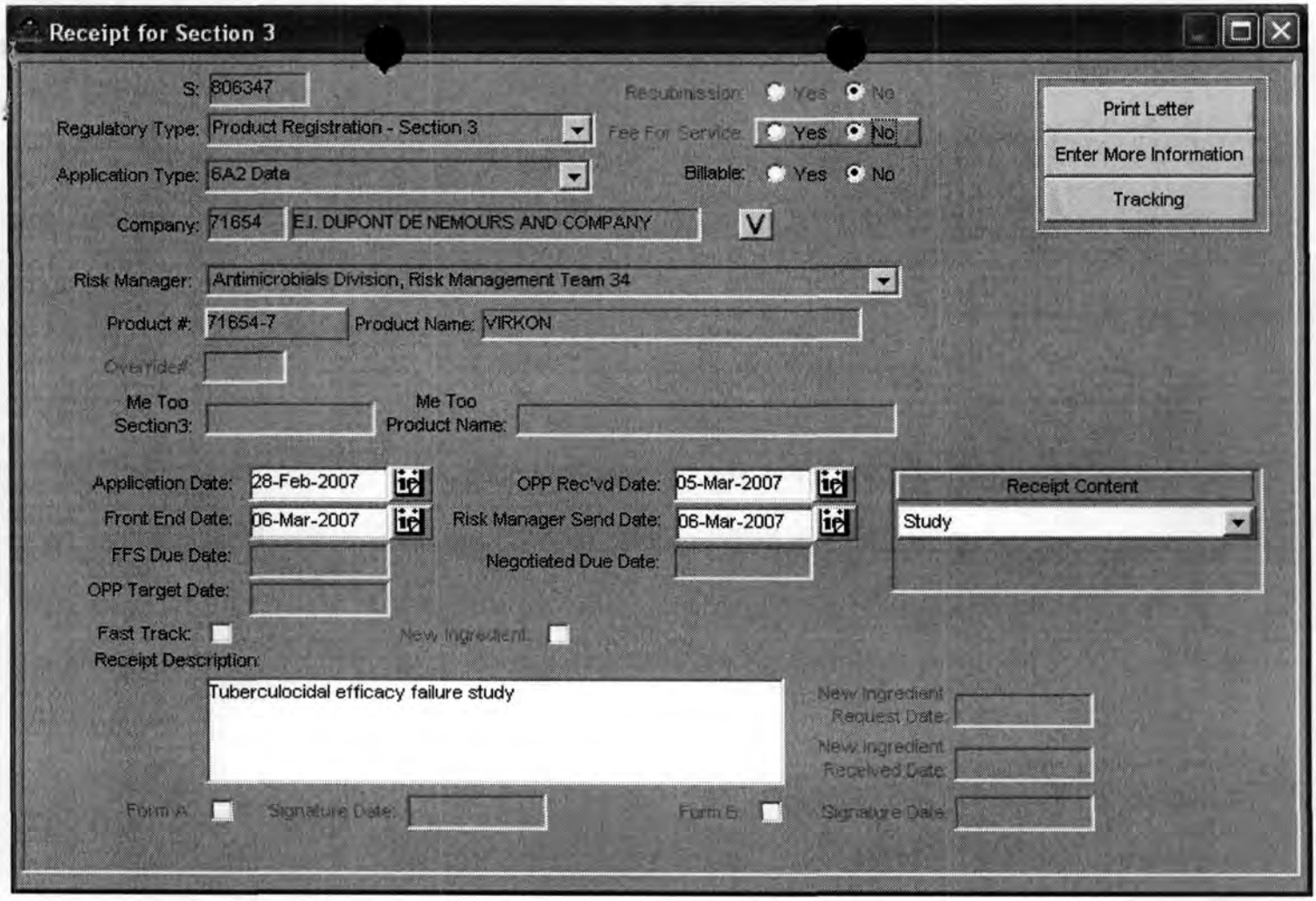
Thank you for your submittal of 05-MAR-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.




Receipt for Section 3
S: 806346
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: 6A2 Data
Billable: Yes No
Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 71654-6
Product Name: VIRKON S
Me Too Section3:
Me Too Product Name:
Application Date: 28-Feb-2007
OPP Rec'vd Date: 05-Mar-2007
Front End Date: 06-Mar-2007
Risk Manager Send Date: 06-Mar-2007
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
Fast Track:
New Ingredient:
Receipt Description:
Tuberculocidal efficacy failure study
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

D378316


Receipt for Section 3
S: 806347
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: 6A2 Data
Billable: Yes No
Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 71654-7
Product Name: VIRKON
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 28-Feb-2007
OPP Rec'vd Date: 05-Mar-2007
Front End Date: 06-Mar-2007
Risk Manager Send Date: 06-Mar-2007
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
Fast Track:
New Ingredient:
Receipt Description:
Tuberculocidal efficacy failure study
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

February 28, 2007

-6 has claims
-7 tested

Document Processing Desk -6(a)(2)
Office of Pesticide Programs- 7504P
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Subject: Information Submitted In Accordance with FIFRA Section 6(a)(2)
40 CFR 159.188(a)(2) Failure of Performance Information
Virkon® S; EPA Reg. No. 71654-6
Potassium Peroxymonosulfate; PC Code 063604

not on label

The attached study was conducted with the EPA registered product, Virkon®; EPA Reg. No. 71654-7. The tested product Virkon® (EPA Reg. No. 71654-7) has the same composition as Virkon® S (EPA Registration No. 71654-6).

The results of this study indicate a failure to support a claim for activity of Virkon® S (EPA Reg. No. 71654-6) against the organism *Mycobacterium bovis*, an organism which "may pose a risk to human health" (40 CFR 159.188(a)(2)).

must be removed

Three copies of the final report, **"H-27069, H-27070 and H-27071:**
47071801 **TUBERCULOCIDAL ACTIVITY OF DISINFECTANTS"** (EPA guideline 810.2100(h)) in PR Notice 86-5 format are attached.

DuPont considers the entire contents of this letter to be subject to protection afforded under FIFRA Section 10(g). Disclosure of this information may be made only in accordance with FIFRA.

If you have any questions, please feel free to contact me by phone or e-mail.

Sincerely,

Thomas C McEntee/KDJ

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

attachments

MEMORANDUM

DATE: 03/07/06

TO: Juanita Cherry for PM 34, Regulatory Manager

FROM: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

TRADE SECRET

MICROBIOTEST, INC

The Microbiology and Virology Laboratory

Volume _____

FINAL REPORT

H-27069, H-27070, and H-27071: TUBERCULOCIDAL ACTIVITY OF DISINFECTANTS

Data Requirements
EPA Guidelines 810.2100 (h)

Author
Jennifer L. Tester

Study Completion Date
February 21, 2007

Performing Laboratory
MICROBIOTEST
105 Carpenter Drive
Sterling, Virginia 20164

Laboratory Project Identification Number
473-119

Sponsor Study Number
DCSE-2007-002

Study Sponsor:
E.I. DUPONT DE NEMOURS AND COMPANY
DuPont Chemical Solutions Enterprise
Experimental Station Laboratory
Building 402/Room 5229B
Wilmington, DE 19880-0402

Pages 227-246 *Access to FIFRA health and safety data is restricted under FIFRA section 10(g)*

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 71654-6

Send to SIG: check box ☐

This material is:

- ☐ New stamped-accepted label
- ☑ New CSF
- ☐ Notification
- ☐ Final Printed Label
- ☐ Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Lisa McKelvy

Phone: 308-7496 Division: AD

Date: 31507

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager

PRODUCT REVIEWER Lisa Mckelvin	RMB II TEAM 34
Description of Action:	EPA File Symbol/Reg No. 71654-6

Decision No. 370210	Submission No. 803732	Fee for Service Action Code:
FQPA Action Code: 362	Non-FQPA Action Code:	PRIA FEE AMOUNT:

	DAY	MONTH	YEAR
APPLICATION DATE	21	December	2006
EPA PIN DATE	07	January	2007
REVIEWER ASSIGNED DATE	13	January	2007
DATE DUE FROM SCIENCE			
DATE DUE TO PM			2007
DATE DUE OUT OF AGENCY			

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure
	■						

COMMENTS: Reply to EPA rejection letter of 11/26/06. Please review.

ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS

B	For Arctic Slope Contract Only	
	Contract No.: 0052	*ARCTIC SLOPE*/MANAGER
	Final Task: Signature _____	_____ (Total hrs)
C	Reviewer Comments:	

DATE FEE PAID:	RESPONSE CODE: 1130 RESPONSE DATE: 03-14-07

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 14, 2007

Thomas C. McEntee
Product Registration Manager
DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: **Virkon S**
EPA Registration Number 71654-6
Letter Dated: December 21, 2006
Receipt Date: January 7, 2007

Dear Mr. McEntee:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is not acceptable for the following reasons.

Proposed Amendment

- Revised alternate formulas (see CSF dated 12/22/06)

Product Chemistry Deficiencies

The following deficiencies refer to the basic pink formula:

1. The concentrations of the active ingredients cannot be determined because the entry in box 17 of the CSF does not agree with the calculated value.

2. The certified limits of all ingredients cannot be determined because the entry in box 17 does not agree with the calculated value.

The following deficiencies refer to the basic pink tablet formula:

1. The concentration of the active ingredient of sodium chloride is not consistent with the label declaration. You must change the label declaration from 1.50 to 1.5.

2. The certified limits cannot be determined because the percentages of all ingredients with the exception of the [redacted] disagree with the calculated values.

General Comment

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or via email at heyward.adam@epa.gov or Lisa McKelvin at (703) 308-7496 or via email at mckelvin.lisa@epa.gov.

Sincerely,

Lisa McKelvin

for

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

February 28, 2007

DP BARCODE: D335356

MRID:

SUBJECT: Virkon S

REG. NO. OR FILE SYMBOL: 71654-6

DOCUMENT TYPE: **Product Chemistry Review**

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS (PC Codes): 063604, 013905

CAS Number: 10058-23-8, 7647-14-5

TEST LAB:

SUBMITTER: E.I. Dupont de Nemours and Company

GUIDELINE:

COMMODITIES:

REVIEWER: Chris Jiang **ORGANIZATION: AD**

APPROVER: Karen P. Hicks **APPROVED DATE:** 2/28/07

COMMENT:

TO: **Adam Heyward\Lisa McKelvin**
PM Team 34

FROM: Chris Jiang, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

CJ

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: E.I. Dupont de Nemours and Company
Action code : 362
Due out date : 4/8/07

Product Formulation	
Active Ingredient(s):	**% by wt.**
Potassium peroxymonosulfate	**21.41 %**
Sodium chloride	**1.50 %**

BACKGROUND: The registrant has submitted a label and Confidential Statements of Formula for alternate formulations (basic pink and basic pink tablet) of this disinfectant.

FINDINGS:

1. The following comments apply to the basic pink formula dated 12/22/06:
   a. The concentrations of the active ingredients cannot be determined because the entry in box 17 of the CSF disagrees with the calculated value.
   b. All ingredients are cleared for use in pesticidal products.
   c. The certified limits of all ingredients cannot be determined because the entry in box 17 disagrees with the calculated value.

2. The following comments apply to the basic pink tablet formula dated 12/22/06:
   a. The concentration of the active ingredient of potassium peroxymonosulfate is consistent with the label declaration; however, the concentration of the active ingredient of sodium chloride is inconsistent with the label declaration. The registrant may wish to change the label declaration from 1.50 to 1.5.
   b. All ingredients are cleared for use in pesticidal products.
   c. The certified limits cannot be determined because the percentages of all ingredients with the exceptions of the [redacted] disagree with the calculated values.

CONCLUSIONS:

1. Product Science Branch of Antimicrobials Division finds the submission for 71654-6 to be unacceptable for the reasons listed in the findings. The registrant must remedy the discrepancies discussed in the findings.

DATA PACKAGE BEAN SHEET

Decision #: 370210
DP #: (335356)

Date: 10-Jan-2007

* * * Registration Information * * *

Registration: 71654-6 - VIRKON S

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

FQPA

Risk Manager: RM 34 - Adam Heyward - (703) 308-6422 Room# PY1 S-8238

Risk Manager Reviewer: Lisa McKelvin LMCKELVI

Sent Date: _____ Calculated Due Date: 08-Apr-2007 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE;TECHNICAL;

Ingredients: 013905, Sodium chloride(1.5%)

063604, Potassium peroxymonosulfate(20.4%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 10-Jan-2007 Due Back: _____

DP Ingredient: 013905, Sodium chloride

063604, Potassium peroxymonosulfate

DP Title: _____

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #: _____

Assigned To	Date In	Date Out	
Organization: AD / PSB	1/10/07		Last Possible Science Due Date: 12-Oct-2006
Team Name: CTT	1/10/07		Science Due Date: 1/11/07
Reviewer Name: CHRIS	1/10/07		Sub Data Package Due Date: 1/26/07
Contractor Name:			

EO
LO

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Product Chemistry: Please review the attached revised alternate CSFs (#s 1 & 2) resubmitted in response to Agency ltr dated 11/26/06

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

DuPont Chemical Solutions Enterprise

December 21, 2006

Document Processing Desk
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Mr. Adam Heyward (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Alternate #1 [Basic Pink Formula]
Alternate #2 [Basic Pink Tablet Formula]

Dear Mr. Heyward,

This letter and its attachments make up our response to your rejection letter of November 26, 2006. Please refer to the two attached CSF's corrected in accordance with your letter.

1. The CAS number has been changed from 70693-62-8 to 10058-23-8 corresponding to the active ingredient potassium peroxymonosulfate.

2. The CAS number for the proprietary inert has been deleted per your request.

3. The total percentage equals 100%

4. The supplier of [redacted] has submitted the full composition directly to EPA.

5. The Alternate formulas are designate "Alternate #1" and "Alternate #2".

6. Your suggestion to change the number of significant digits from four to three has been implemented for the certified limits column. Making this change on the label ingredient statement is still under consideration.

Should you have any questions, feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856